VELTEK ASSOCIATES, INC.

INNOVATIVE CLEAN ROOM SOLUTIONS

CLEANERS,
DISINFECTANTS
& SPORICIDES
via VAI's Extensive and Unique Product Line
CAPTURE CONTAMINATION
via the SMA Microbial Air Sampler Systems
FULL CIRCLE
APPROACH
ID CONTAMINATION
Genetic Sequencing via VAI Laboratories
PERSONNEL GOWNING
via VAI's PF-2 and Mitcool Product Line
DISINFECTANT
& CIP CLEANER
VALIDATION
via VAI Laboratories or CORE Labs
CONSULTING &
TRAINING SERVICES
Aseptic Processing, Inc.
API
Aseptic Processing Inc.
CORE
APPLICATION DEVICES
Core2Clean and Bucket Systems

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COMPANY AT A GLANCE

Founded:	1981
Headquartered:	Malvern, Pennsylvania (suburban Philadelphia)
Customers:	More than 300 worldwide
Employees:	120
Key Business Lines:	Sterile Chemicals & Disinfectants, Microbial Air Sampling, Clean Disposable Garments, Sterile Ingredients, Consulting
VAI Laboratories:	In-house testing & research facility
Registrations:	FDA, EPA
Web Site:	www.sterile.com
Phone:	610-644-8335

INNOVATIVE SOLUTIONS YOU CAN TRUST

Every day, the people of Veltek Associates, Inc. make amazing things happen—from revolutionary discoveries to exceptional customer service to consistent, quality manufacturing. As a result, we remain the clean room industry's most trusted source for innovation, quality and service…

For more than 25 years, Veltek Associates, Inc. (VAI), headquartered in Malvern, Pa., has pioneered the design and manufacture of hundreds of clean room solutions. These innovations, many of them landmarks in the industry's history, allow our customers to overcome challenges and reach their business goals. Plus, VAI clients have more than a solutions provider; they have a partner and trusted advisor. And with today's complex research challenges, new competition and increasing government regulations, a true partnership is more important than ever.

In 1981, Arthur L. Vellutato, Sr. founded VAI after 25 years in the pharmaceutical industry. VAI made an immediate contribution to the industry as the first to manufacture disposable garments from start to finish in a clean room environment. Since then, VAI's product line has diversified significantly, enabling us to find solutions for many types of contamination, and for use in many industries. Our divisions include sterile manufacturing chemicals, environmental control monitoring and disposable products. In addition, VAI Laboratories provides our customers with microbiological testing services ranging from the identification of microorganisms to antimicrobial effectiveness studies.

We invite you to learn more about VAI's products and services, and see for yourself what makes us the most innovative and responsive provider in the industry. Whether you are looking for the tried-and-true products that helped build your business or looking to develop something brand new, VAI provides innovative solutions you can trust.

A HISTORY OF INNOVATION

For us, it's simple. Innovation is about listening to industry challenges and not stopping until we find the answer. Together with our clients, we've been developing new solutions for the clean room industry for more than 25 years.

Our products and services have allowed our clients to do remarkable things—from biotechnology breakthroughs to pharmaceutical discoveries that help millions of people every day. From our early days developing the first sterile garments to our latest innovations, VAI develops products that revolutionize and simplify aseptic manufacturing. We encourage you to discuss your needs with our technical representatives by calling 610-644-8335.

1981

In 1981, we produced the first disposable garments manufactured, from start to finish, in a clean room environment. From that point on, manufacturers were assured the cleanliness of the final product.

Four years later, in 1985, we designed the SMA®, the first microbial air sampler that could be completely sterilized.

In 1993, VAI scientists developed DEC-AHOL®, the first 0.2 micron filtered alcohol that was irradiated sterile in a non-aspirating aerosol spray container and in bulk containers. That same year, we developed the first sterilized disinfectants, and sporicides that were filtered at 0.2 microns and packaged into unidose and bulk containers.

In 1996, we introduced the first 0.2 micron-filtered and sterilized clean room lubricants, bringing a new level of flexibility and security to clean room environments.

PROCESS2CLEAN
FOR CRITICAL CLEAN IN PLACE APPLICATIONS

CAGE2WASH

2007

In 1997, we designed and manufactured the first sterile ingredients for use in parenteral manufacturing and introduced the first computerized microbial air sampling system.

In 2003, VAI developed the Simplemix® System, the first sealed multi-chamber container that houses both WFI Quality Water and a sporicide or disinfectant—simply pull a tab and they instantly mix together.

In 2006, the complete line of Process2Clean® products are released. Designed specifically for critical clean in place applications, the products are VAI's most effective solution for removing product residues and helping assure against contamination.

KNOWLEDGE, EXPERIENCE AND PARTNERSHIP

More than 300 pharmaceutical, biotechnology and healthcare clients around the world turn to VAI because we understand the challenges they face. Our experience and unsurpassed technical expertise means "real-world" solutions from people who have worked in the industry. And, because our product line is so extensive, a relationship with VAI means a more cost-effective way to buy clean room products.

At VAI, we develop our products in an environment that mimics your environment — providing a seamless development process that ensures accuracy and precision. And when you work with us, you get recommendations from technical experts who have extensive industry experience, not salespeople. This means you get exactly what you need, and nothing you don't.

About VAI Laboratories

Complete and documented efficacy performance and testing to prove the removal of existent contamination is a very costly and time-consuming task. Hence, VAI has responded by establishing VAI Laboratories, a GLP microbiological testing facility capable of performing time contact kill studies, disinfectant validation services and microbe identification. In addition, the VAI Laboratories staff, who work daily in GMP settings, will consult with each client to ensure they achieve best-in-class clean room operations and contamination control. These value-added services provide our clients with timely advice and proven solutions, all within the framework of regulatory requirements.

Learn More

At VAI, we strive to develop meaningful, long-term relationships with our clients to help reduce expenses, eliminate waste and simplify manufacturing. Plus, our products are designed to build upon each other, so as you grow, you know you can count on us. Call us today at 610-644-8335 or visit www.sterile.com.

WELCOME TO SCMD

STERILE CHEMICAL MANUFACTURING DIVISION

The prior removal of contaminants, both viable and non-viable, in solutions to be used within the aseptic manufacturing operation is essential in assuring the control and integrity of the environment.

VAI's Sterile Chemical Manufacturing Division (SCMD) has addressed the needs of the Pharmaceutical and Biotechnology industries by designing a complete range of sterile chemicals and disinfectants for the Class 100 aseptic manufacturing area. VAI's SCMD products are used at over 300 Pharmaceutical and Biotechnology organizations worldwide.

VAI's SCMD manufacturing operations mirror Current GMP's and enforces the complete adherence to USP specifications for testing of all manufactured products. VAI is also an EPA and FDA registered facility.

SCMD occupies a majority of the square footage of the Malvern, PA facility and manufactures a complete range of sterile chemicals and disinfectants that are used daily in Class 100 operations. All VAI manufacturing operations are completely validated and routinely revalidated to assure product integrity. VAI capabilities for manufacturing products include the ability to fill aerosol, bulk and unidose packages in a Class 100 aseptic filling operation. Our aseptic filling operations are coupled with the validated and proven ability to irradiate a final product. Assurances are taken in every aspect of SCMD concerning sterility and particulate removal.

SCMD has taken another step in product quality assurance by incorporating USP Water for Injection (WFI) into some of our products. The established WFI systems in our new SCMD facility incorporate an added advantage to the manufacture of our products. The mission of VAI's SCMD is to provide either a pyrogen free product where desired or a pyrogen reduced product where raw materials that must be incorporated have the inability to be processed as pyrogen free.

SCMD has manufacturing capabilities to produce both VAI products and custom contract manufacturing designs. In recent years, VAI has been asked by many Pharmaceutical and Biotechnology operations to manufacture raw materials for use in their operation. VAI's SCMD uncompromising cGMP manufacturing style and our complete adherence to USP specifications have assured outside organizations that their products will not only be produced and tested as sterile, but moreover, their product will be completely documented and validated. VAI's SCMD is proud of its history and track record.

VAI's SCMD® products include DEC-AHOL® Sterile WFI, STER-AHOL® Sterile WFI, DEC HAND®, DEC-PHENE®, DEC-PHASE®, DEC-CYCLE®, PHENE-AHOL®, DEC-Clean®, DEC-QUAT®, HYPO-CHLOR®, STERI-PEROX®, STERI-WATER®, VAI WFI QUALITY WATER, DEC-SPORE 200 Plus®, DEC-Glass®, STERI-OIL®, STERI-SILICON®, STEEL-BRIGHT® and the SIMPLEMIX® product line.

These products are described on the following pages.

SCMD-STERILE CHEMICAL MANUFACTURING DIVISION

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33	STERI-SILICON
34	STEEL-BRIGHT & DAS-WIPE 100
35	DEC-GLASS
36	DEC-SOAP

610-644-8335

DEC-ASSURE® BIODECONTAMINATION PROGRAM

The DEC-Assure Biodecontamination Program has been developed to assist you in maintaining acceptable environmental conditions while addressing the requirements of regulatory agencies. "Testing and Addressing" contamination in a documented system is the goal of the DEC-Assure Biodecontamination Program. The following is a brief summary.

CRITERIA #1: TEST AND ADDRESS CONTAMINATION:

Through one's environmental monitoring program, one can develop a list of environmental isolates that have been noticed in their operations. Once developed, the key is to successfully integrate and document a plan for assuring the demise of these organisms.

CRITERIA #2: ANTIMICROBIAL EFFECTIVENESS STUDIES:

Determining what chemical agents will destroy a known level of one's environmental isolates is the next step. Prior to conducting either a Time Contact Kill Study (Tube Dilution), or a Time Contact Kill Study (On User Surfaces) or an AOAC Protocol Study, one needs to review the available disinfecting agents and determine which is initially appropriate for their operations. Upon choosing 1 or 2 disinfecting agents and a sporicide, one can continue with the antimicrobial effectiveness studies. Antimicrobial effectiveness studies must be based on realistic bioburdens that may be noticed in the controlled areas. It is normal to test an enumeration greater than or equal to 1.0 x 104 cfu's. This testing will provide the justification for utilizing the chemical agents.

CRITERIA #3: CHOOSING A DISINFECTION SYSTEM:

Varying applications require various solutions to be in place. VAI has established three (3) systems that will net success. The choice to use a phenolic, quaternary ammonium or hydrogen peroxide delineates the rotation parameters. The choice of one disinfectant and a sporicide is completely appropriate, however, some may decide to rotate similar disinfectants while also utilizing a sporicide.

DEC-ASSURE® BIODECONTAMINATION PROGRAM (CONTINUED)

Rotation systems are designed to address known or possibly existent contamination with proven efficacious disinfectants. The basis for the rotation of disinfecting or sporicidal agents is to address an organism that may not be destroyed by a particular disinfectant with another that has proven efficacy performance against such organism. An example would be a phenol that may not kill a b. subtillis in a 5-10 minute contact time and thus the rotation to a more efficacious product such as a sporicide may be warranted to destroy this organism. However, organisms do not develop an immunity or resistance to a chemical agent over time. Scientific evidence of such occurrences has never been documented as factual in the clean room. Thus, the basis for rotation is to address an organism that is not destroyed by, nor ever was destroyed by, one chemical agent with another that has proven efficacy performance against such organism.

Destroying contamination in a clean room operation requires addressing the known vegetative cells and the spores. In design of a rotation system, there are two types. 1) A single disinfectant rotated with a sporicide, and 2) A two disinfectant system (rotated monthly) plus a sporicide. Either system requires, at minimum, a monthly sporicidal application. This may be increased or decrease in time frames and will be determined by the environmental conditions. The use of DEC-Clean® is considered an optional step in controlling existent residues and should be done at least once a quarter (suggested monthly). DEC-AHOL WFI® or STER-AHOL WFI® should be used on process equipment as a final wipe down.

CRITERIA #4: CONDUCTING AN "IN-SITUATION FIELD STUDY":

Once a disinfection system has been chosen and antimicrobial effectiveness testing has been completed, conducting an “in situation field study” is important to prove the effectiveness of the combination of our cleaning SOP’s (standard operating procedures) and our antimicrobial effectiveness testing. Simply, environmental monitoring (both air and surface) is conducted in a dirtied room. Upon completion of the monitoring, the room is cleaned and disinfected per the current operating procedures. Upon completion and drying of all surfaces, the room is monitored again. Satisfactory results need to be obtained in 3 different and separate in-situation field studies prior to acceptance of the disinfection system.

CRITERIA #5: UPDATING YOUR PROFILE:

As time progresses, it’s possible that not previously tested organisms may be noticed in operations. Antimicrobial effectiveness testing should be performed on these contaminants to continue to prove and document the disinfection system as validated to current operations. Changes over time may also occur in production scenarios, processes and personnel. Reviewing SOP’s for cleaning and disinfection should be done routinely to address current situations.

DEC-ASSURE® BIODECONTAMINATION PROGRAM (CONTINUED)

DEC-ASSURE ROTATION SYSTEMS:

Month 1: Rotating One Disinfectant and a Sporicide

Day(s)	Phenolic	Quaternary Ammonium	Hydrogen Peroxide
Day 1-13	DEC-PHENE, DEC-PHASE or DEC-CYCLE	DEC-QUAT	STERI-PEROX 3% or 6%
Day 14 (if warranted by EM data)	DEC-Clean followed by HYPO-CHLOR 0.52% or STERI-PEROX 3% or 6%, or DEC-SPORE 200 Plus.	DEC-Clean followed by HYPO-CHLOR 0.52% or STERI-PEROX, or DEC-SPORE 200 Plus.	DEC-Clean followed by HYPO-CHLOR 0.52% or STERI-PEROX, or DEC-SPORE 200 Plus.
Day 15-29	DEC-PHENE	DEC-QUAT	STERI-PEROX 3% or 6%
Day 30	DEC-Clean followed by HYPO-CHLOR 0.52% or STERI-PEROX, or DEC-SPORE 200 Plus.	DEC-Clean followed by HYPO-CHLOR 0.52% or STERI-PEROX, or DEC-SPORE 200 Plus.	DEC-Clean followed by HYPO-CHLOR 0.52% or STERI-PEROX, or DEC-SPORE 200 Plus.

Month 2: Rotating Two Disinfectants with a Sporicide

Day(s)	Phenolic	Quaternary Ammonium	Hydrogen Peroxide
Day 1-13	DEC-PHENE, DEC-PHASE or DEC-CYCLE	DEC-QUAT	STERI-PEROX 3% or 6%
Day 14 (if warranted EM data)	DEC-Clean followed by HYPO-CHLOR 0.52% or STERI-PEROX 3% or 6%, or DEC-SPORE 200 Plus.	DEC-Clean followed by HYPO-CHLOR 0.52% or STERI-PEROX 3% or 6%, or DEC-SPORE 200 Plus.	DEC-Clean followed by HYPO-CHLOR 0.52% or by STERI-PEROX 3% or 6%, or DEC-SPORE 200.
Day 15-29	DEC-CYCLE	STERI-PEROX 3% or 6%	DEC-QUAT
Day 30	DEC-Clean followed by HYPO-CHLOR 0.52% or STERI-PEROX 3% or 6%, or DEC-SPORE 200 Plus.	DEC-Clean followed by HYPO-CHLOR 0.52% or STERI-PEROX 3% or 6%, or DEC-SPORE 200 Plus.	DEC-Clean followed by HYPO-CHLOR 0.52% or STERI-PEROX 3% or 6%, or DEC-SPORE 200 Plus.

After disinfection all critical surfaces should be rinsed with hot WFI or an IPA wipedown performed.

DEC-AHOL® STERILE WFI

WFI FORMULA USP ISOPROPYL ALCOHOL WITH USP WFI WATER

DEC-AHOL Sterile WFI Formula has been developed to address the reduction of possible endotoxin levels that may exist in the use of a 70% sterile Isopropyl alcohol solution. VAI knew that just formulating 99% isopropyl alcohol with USP Water for Injection (WFI) without the concern for the reduction of endotoxin levels throughout the entire manufacturing process would net an unacceptable final product. Therefore, after years of development VAI has assured not only the formulation of the product with UPS Water for Injection but also designed a system to assure a closed system manufacture of the product. VAI has assured the lowest possible endotoxin level making it an excellent choice for the critical Class 100 aseptic manufacturing operation.

DEC-AHOL WFI Formula is:

- 70% USP Isopropyl Alcohol
- Filtered at 0.2 Microns
- Double-bagged packaged
- Gamma irradiated
- Completely tested according to current USP compendium
- Delivered with lot specific Certificate of Irradiation, Certificate of Analysis, LAL Testing Analysis and Sterility Report
- Completely traceable
- Completely validated for sterility and shelf life

USES: DEC-AHOL WFI Sterile Formula is used for the decontamination of items such as:

- Gloves
- Surfaces
- Carts
- Countertops
- Process lines
- Applications that require a sterile alcohol solution made with USP Water for Injection

Order#	Description	Quan/cs.
DECWFI-SP-70-E	70% Mist Spray Sterile, 11 oz. Aerosol	24
DECWFI-ST-70-E	70% Stream Spray Sterile, 11 oz. Aerosol	24
DECWFI-SP-70-B-E	70% Inverta Spray Mist, 11 oz. Aerosol	24
DECWFI-SP-91-E	91% Mist Spray Sterile, 11 oz. Aerosol	24
DECWFI-ST-91-E	91% Stream Spray Sterile, 11 oz. Aerosol	24
DECWFI-B-60-E	60% 1 Gallon Sterile	4
DECWFI-B-70-E	70% 1 Gallon Sterile	4
DECWFI-B-91-E	91% 1 Gallon Sterile	4
DECWFI-TR-03-E	70% 16 oz. Trigger Spray Sterile (separate triggers)	12
DECWFI-TR-04-E	70% 16 oz. Trigger Spray Sterile (attached triggers)	12
DECWFI-TR-05-E	70% 32 oz. Trigger Spray Sterile (attached triggers)	12
DECWFI-SQ-8Z-E	70% 8 oz. Squeeze Bottle Sterile	24
DECWFI-SQ-16Z-E	70% 16 oz. Squeeze Bottle Sterile (individually bagged)	12
DECWFI-SQ-03-E	70% 16 oz. Squeeze Bottle Sterile (bulk packed)	12
DECWFI-B-5G-70-E	70% 5 Gallons Container Sterile	1
DECWFI-BAG-01-E	70% 32 ounce bag for Asepti Cleanse® unit	8

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

DEC-AHOL WFI Product Validation
Technical Data File

610-644-8335

STER-AHOL® STERILE WFI

DENATURED ETHANOL WITH USP WFI WATER

STER-AHOL Sterile WFI Formula is 70% Denatured Ethanol made with USP Water for Injection

STER-AHOL WFI Formula is:

- Filtered at 0.2 Microns
- Double-bagged packaged
- Gamma irradiated
- Formulated to 70% and denatured with a small percentage of Methyl Alcohol and Isopropyl Alcohol
- Available in aerosol spray (nitrogen propellant), 16 ounce containers and 1-gallon containers
- Completely tested according to current USP compendium
- Delivered with lot specific Certificate of Irradiation, Certificate of Analysis, LAL Testing Analysis and Sterility Report
- Completely traceable
- Completely validated for sterility and shelf life

USES: STER-AHOL WFI Sterile Formula is used for the decontamination of items such as:

- Gloves
- Surfaces
- Carts
- Countertops
- Aseptic connections
- Applications that require a sterile alcohol solution made with USP Water for Injection

Order#	Description	Quan/cs.
DSTER-WFI-SP-70	70% 11 oz. Aerosol Mist Spray Sterile	24
DSTER-WFI-B-70	70% 1 Gallon Sterile	4
DSTER-WFI-TR-04	70% 16 oz. Trigger Spray Sterile	12

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

STER-AHOL WFI Product Validation
Technical Data File

SIMPLEMIX® SYSTEMS

For the Exact Formulation of Disinfectants and Sporicides.

ADVANTAGES AND FEATURES:

- Eliminates concerns by regulatory agencies for proper mixing and sterility of the solution
- No filtering solutions to aseptic manufacturing areas
- No need to assure sterile USP Water For Injection is present in the aseptic area
- No concerns for mixing and handling concentrate phenolics, quaternary ammoniums, per acetic acid & H202 or cleaners with sterile water in aseptic manufacturing operations
- The system assures the appropriate dilution is made each time in a closed sterile system
- Dilutions are made safely as concentrates are never handled
- All chemical agents and the WFI Quality Water, are filtered at 0.2 microns and manufactured in a Class 100 filling operation
- The contents of the double bagged package are sterilized through a validated gamma radiation cycle that assures a 10^{-6} Sterility Assurance Level
- All product lots are sterility tested per current USP compendium
- Available in 2 sizes – 1 gallon and 16 ounce trigger sprayer
- Simply remove the top cap, pull the tab, replace the cap and shake gently. The solution is then ready to use
- Available Sterile and Non-Sterile in the following VAI products:
  - DEC-PHENE®
  - DEC-CYCLE®
  - DEC-PHASE®
  - DEC-QUAT 100®
  - DEC-Clean®
  - DEC-SPORE 200 Plus®

1 GALLON STERILE

Order#	Description	Quan/cs.
DP-04-1Z-E	DEC-PHENE 1:128 use dilution 1 gal. mixture	4
DPH-04-1/2-Z-E	DEC-PHASE 0.5:128 use dilution 1 gal. mixture	4
DCY-04-1/2Z-E	DEC-CYCLE 0.5:128 use dilution 1 gal. mixture	4
DQ100-04-2Z-E	DEC-QUAT 2:128 use dilution 1 gal. mixture	4
DC-04-1Z-E	DEC-Clean 1:128 use dilution 1 gal. mixture	4
DS200-04-1/2ZA-E	DEC-SPORE 200 Plus 0.5:128 use dilution 1 gal. mixture	4
DS200-04A-E	DEC-SPORE 200 Plus 6.4:128 use dilution 1 gal. mixture	4

1 GALLON NON-STERILE

Order#	Description	Quan/cs.
DP-05-1Z-E	DEC-PHENE 1:128 use dilution 1 gal. mixture	4
DPH-05-1/2Z-E	DEC-PHASE 0.5:128 use dilution 1 gal. mixture	4
DCY-05-1/2Z-E	DEC-CYCLE 0.5:128 use dilution 1 gal. mixture	4
DQ100-05-2Z-E	DEC-QUAT 2:128 use dilution 1 gal. mixture	4
DC-05-1Z-E	DEC-Clean 1:128 use dilution 1 gal. mixture	4
DS200-05-1/2ZA-E	DEC-SPORE 200 Plus 0.5:128 use dilution 1 gal. mixture	4
DS200-05A-E	DEC-SPORE 200 Plus 6.4:128 use dilution 1 gal. mixture	4

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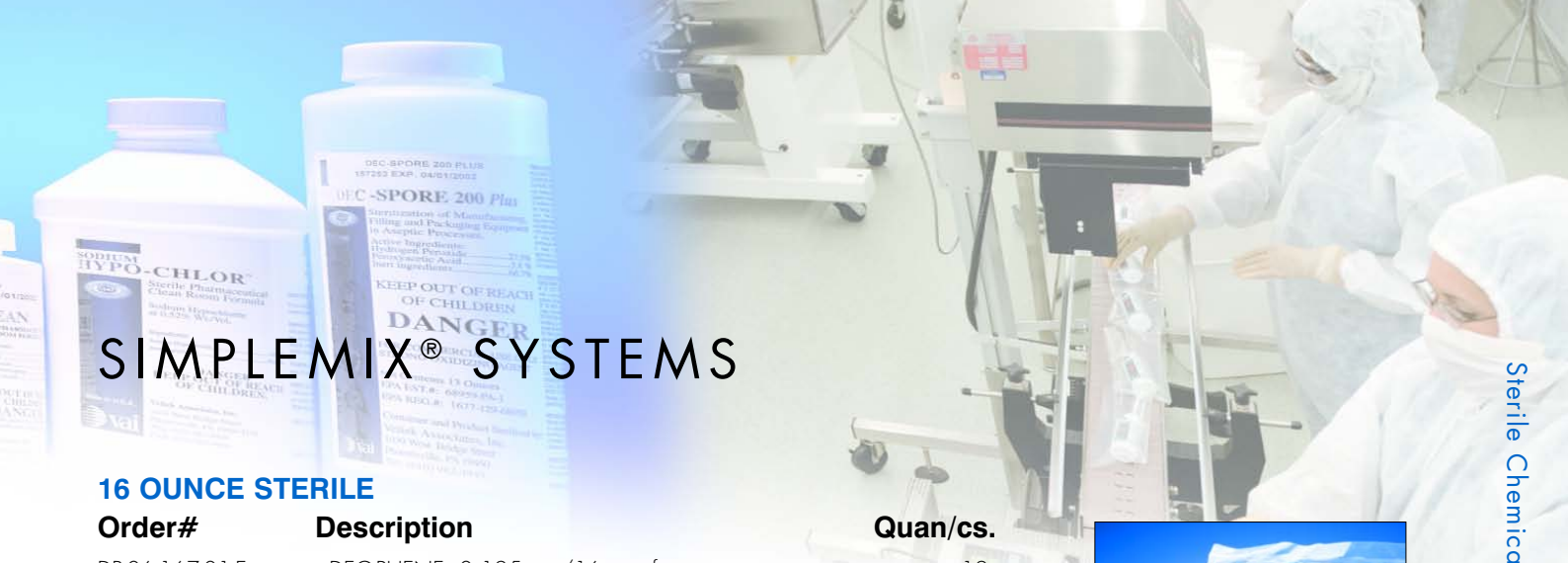


SIMPLEMIX® SYSTEMS

16 OUNCE STERILE

Order#	Description	Quan/cs.
DP-06-16Z-01-E	DEC-PHENE 0.125 oz./16 oz of water	12
DP-06-16Z-02-E	DEC-PHENE 0.250 oz./16 oz of wate	12
DCY-06-16Z-01-E	DEC-CYCLE 0.0625 oz./16 oz of water	12
DCY-06-16Z-02-E	DEC-CYCLE 0.125 oz./16 oz of water	12
DPH-06-16Z-01-E	DEC-PHASE 0.0625 oz./16 oz of water	12
DQ100-06-16Z-01-E	DEC-QUAT 0.250 oz./16 oz of water	12
DS200-06-16Z-01-E	DEC-SPORE 200 Plus Sterilant 0.8/16 oz of water	12
DS200-06-16Z-02-E	DEC-SPORE 200 Plus Disinfectant 0.0625 oz./16 oz of water	12
DC-06-16Z-01-E	DEC-Clean 0.125 oz./16 oz of water	12

16 OUNCE NON-STERILE

Order#	Description	Quan/cs.
DP-07-16Z-01-E	DEC-PHENE 0.125 oz./16 oz of water	12
DP-07-16Z-02-E	DEC-PHENE 0.250 oz./16 oz of water	12
DCY-07-16Z-01-E	DEC-CYCLE 0.0625 oz./16 oz of water	12
DCY-07-16Z-02-E	DEC-CYCLE 0.125 oz./16 oz of water	12
DPH-07-16Z-01-E	DEC-PHASE 0.0625 oz./16 oz of water	12
DQ100-07-16Z-01-E	DEC-QUAT 0.250 oz./16 oz of water	12
DS200-07-16Z-01-E	DEC-SPORE 200 Plus Sterilant 0.8/16 oz of water	12
DS200-07-16Z-02-E	DEC-SPORE 200 Plus Disinfectant 0.0625 oz./16 oz of water	12
DC-07-16Z-01-E	DEC-Clean 0.125 oz./16 oz of water	12

32 OUNCE STERILE

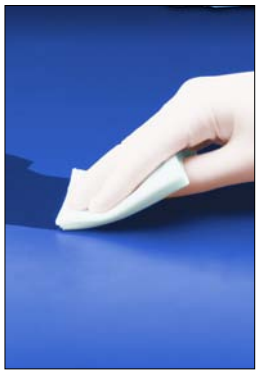
Order#	Description	Quan/cs.
DP-08-32Z-01-E	DEC-PHENE 32 oz. 0.25 oz./gallon of water Sterile	8
DP-08-32Z-02-E	DEC-PHENE 32 oz. 0.50 oz./gallon of water Sterile	8
DP-09-32Z-01-E	DEC-PHENE 32 oz. 0.25 oz./gallon of water Non-Sterile	8
DP-09-32Z-02-E	DEC-PHENE 32 oz. 0.50 oz./gallon of water Non-Sterile	8
DCY-08-32Z-01-E	DEC-CYCLE 32 oz.0.125 oz/gallon of water Sterile	8
DCY-08-32Z-02-E	DEC-CYCLE 32 oz 0.25 oz/gallon of water Sterile	8
DCY-09-32Z-01-E	DEC-CYCLE 32 oz 0.125 oz/gallon of water Non-Sterile	8
DCY-09-32Z-02-E	DEC-CYCLE 32 oz 0.25 oz/gallon of water Non-Sterile	8
DPH-08-32Z-01-E	DEC-PHASE 32 oz.0.125 oz/gallon of water Sterile	8
DPH-09-32Z-02-E	DEC-PHASE 32 oz.0.125 oz/gallon of water Non-Sterile	8
DQ100-08-32Z-01-E	DEC-QUAT 32 oz.0.50 oz/gallon of water Sterile	8
DQ100-09-32Z-02-E	DEC-QUAT 32 oz.0.50 oz/gallon of water Non-Sterile	8
DS200-08-32Z-01-E	DEC-SPORE 200 Plus 32 oz.0.125 oz./gallon of water Sterile	8
DS200-08-32Z-02-E	DEC-SPORE 200 Plus 32 oz.1.6 oz./gallon of water Sterile	8
DS200-09-32Z-01-E	DEC-SPORE 200 Plus 32 oz.0.125 oz./gallon of water Non-Sterile	8
DS200-09-32Z-02-E	DEC-SPORE 200 Plus 32 oz.1.6 oz./gallon of water Non-Sterile	8

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

SimpleMix Product Validation
Technical Data File

ALCOH-WIPE® & ALCOH-GLOVE® STERILE SINGLES

SATURATED WITH 70% USP ISOPROPYL ALCOHOL



ALCOH-WIPE, & ALCOH-GLOVE, are designed for sterile operations that demand the use of an individually packaged sterile saturated wipe.

ALCOH-WIPE IS:

- Saturated with DEC-AHOL®, WFI 70% USP Isopropyl Alcohol
- Individually packaged sterile wipe
- Available in a variety of sizes:
  - 6 inch x 6 inch
  - 12 inch x 12 inch
  - 18 inch x 18 inch
- A polyester blend that is inherently low in particulate and shedding features
- Excellent for pharmaceutical and biotechnology industries
- Filtered at 0.2 Microns
- Gamma irradiated through a validated cycle
- Delivered with lot specific Certificate of Irradiation, Certificate of Analysis and Sterility Test Report
- Completely validated for sterility and shelf life

ALCOH-GLOVE IS:

- Remarkable innovation that resembles a dust mitten
- A non-linting, non-shedding polyester tube that is sewn at one end and then turned inside out
- Contoured to provide 100% coverage of the hand
- Saturated with DEC-AHOL WFI 70% USP Isopropyl Alcohol
- Individually packaged sterile wipe
- Filtered at 0.2 Microns
- Gamma irradiated through a validated cycle
- Delivered with lot specific Certificate of Irradiation, Certificate of Analysis and Sterility Test Report
- Completely traceable
- Completely validated for sterility and shelf life

Order#	Description	Quan/cs.
VEL6-6X6	ALCOH-WIPE 6" X 6" Flat Wipe Non-Sterile	100
VEL6-6X6-S	ALCOH-WIPE 6" X 6" Flat Wipe Sterile	100
VEL6-12X12	ALCOH-WIPE 12" X 12" Flat Wipe Non-Sterile	100
VEL6-12X12-S	ALCOH-WIPE 12" X 12" Flat Wipe Sterile	100
VEL6-18X18	ALCOH-WIPE 18" X 18" Flat Wipe Non-Sterile	100
VEL6-18X18-S	ALCOH-WIPE 18" X 18" Flat Wipe Sterile	100
VEL12-12x12x12-S	ETHANOL-WIPE 12" X 12" Flat Wipe Sterile	100
AG-02	ALCOH-GLOVE Contoured Wipe Non-Sterile	100
AG-04	ALCOH-GLOVE Contoured Wipe Sterile	100

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

AHOL-WIPE/ALCOH-GLOVE Product Validation
Technical Data File

DEC-HAND®

INSTANT HAND SANITIZER

DEC-HAND is a gelled alcohol hand sanitizer for hand washing to decrease bacteria on the skin.

DEC-HAND:

- Is used by applying thoroughly to the hands and allowed to dry without wiping (use no water or towels)
- Is Double-bagged packaged
- Is Gamma irradiated
- Manufactured in accordance with 21 CFR Part 211 Good Manufacturing Practices for DRUGS and the Tentative Final Monograph for Topical Antimicrobial Drug Products for Over-the-Counter use
- Can be used with the DH-100 dispenser/holder system or the Asepti-Cleanse hands-free dispenser
- Is completely tested according to current USP compendium
- Is delivered with lot specific sterile documentation
- Is completely validated for sterility and shelf life

USES: DEC-HAND is used as an instant hand sanitizer before glove doning.

Order#	Description	Quan/cs.
DH-04-E	DEC-HAND 16 oz. Non-sterile	12
DH-06-E	DEC-HAND 16 oz. Sterile	12
DH-07-E	DEC-HAND Non-Sterile Hand Sanitizer Bags, 32 oz. (944 mL) *fill for Asepti-Cleanse Dispenser*	8
DH-08-E	DEC-HAND Sterile Hand Sanitizer Bags, 32 oz. (944 mL) fill double bag packaged, filtered at 0.2 microns and gamma irradiated *for Asepti-Cleanse Dispenser*	8
DH-100	DEC-HAND Wall Dispenser (316L Stainless)	1
DH-200	ASEPTI-CLEANSE Dispenser for DEC-AHOL or DEC-HAND *Operates on 4 D-Cell Batteries*	1
DH-201	ASEPTI-CLEANSE Dispenser for DEC-AHOL or DEC-HAND *Operates on 4 D-Cell Batteries or 110V Direct connections*	1

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

DEC-HAND Product Validation
Technical Data File

ASEPTI-CLEANSE®

HANDS-FREE DEC-AHOL® WFI/DEC-HAND® DISPENSER

ASEPTI-CLEANSE dispenser is a hands-free dispenser for DEC-AHOL WFI and DEC-HAND. The system has been designed by VAI as the most advanced infrared sensor dispensing system available in the pharmaceutical and biotechnology industries. The dispensing unit is designed to meet the requirements of cGMP clean room operations.

ASEPTI-CLEANSE Dispensing System:

- Is a sealed unit that protects the coated internal electronics
- Is photo-eye operated. Just place your hand underneath and it dispenses a pre-measured dose to the hand without contact of the person to the unit
- Can be adjusted to dispense 1, 3 or 5 mLs
- Is designed in a dual power configuration of power supply. It can be powered by 4 D Cell batteries (4 D Cells last over 1 year) or connected to a 110 Volt receptacle. In the electrically mounted installation, one has the backup of the battery power if a failure in the power line occurs due to an abnormal situation
- Mounts directly on glass or walls
- Is water resistant in design
- Is small. It measures 12 inch long x 5 inches wide x 2 inches high and has a keyless opening and closing system

Order#	Description	Quan/cs.
DEC-200	ASEPTI-CLEANSE Dispenser for DEC-AHOL or DEC-HAND *Operates on 4 D-Cell Batteries*	1
DEC-201	ASEPTI-CLEANSE Dispenser for DEC-AHOL or DEC-HAND *Operates on 4 D-Cell Batteries or 110V direct connections*	1
DH-07-E	DEC-HAND Non-Sterile Hand Sanitizer Bags, 32 oz. (944 mL) *fill for Asepti-Cleanse Dispenser*	8
DH-08-E	DEC-HAND Sterile Hand Sanitizer Bags, 32 oz. (944 mL) fill double bag packaged, filtered at 0.2 microns and gamma irradiated *for Asepti-Cleanse Dispenser*	8
DECWFI-BAG-01-E	DEC-AHOL WFI Sterile 70% USP IPA Bags, 32 oz. (944 mL) fill double bag packaged, filtered at 0.2 microns and gamma irradiated *for Asepti-Cleanse Dispenser*	8

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

Technical Data File

ALCOHOL DISPENSERS

FOR USE WITH VAI ALCOHOL PRODUCTS

Several options exist to further simplify the dispensing of our DEC-AHOL WFI® and STER-AHOL WFI® products. The hand activated and hands-free dispensing mechanisms (DEC-50 and DEC-100) assure the elimination of cross contamination from user to user during handling of the alcohol container. The bulk container mechanisms (200-P and 300-T) simplify dispensing of the product while delivering dosed quantities to prevent overuse of the product.

DEC-50 Hand-Activated Dispenser:

- Easy back of hand dispensing
- 316L Stainless Steel construction
- Dispensing mechanism easily slides on and off a permanently installed wall plate that incorporates welded pin connectors
- Autoclavable

DEC-100 Hands-Free Dispenser:

- Foot petal operated
- 316L Stainless Steel construction
- Permanently mounts to clean room or gowning area wall
- Incorporates a safety glass over spray protector window and foot petal attached by chain

200-P Gallon Pump Dispenser:

- Attaches to DEC-AHOL WFI and STER-AHOL WFI 1 gallon containers
- Top lever dispenses a specified dose of alcohol
- Double bagged packaged
- Gamma irradiated

300-T Gallon Trigger Sprayer:

- Attaches to DEC-AHOL WFI and STER-AHOL WFI 1 gallon containers
- Trigger sprayer dispenses a specified dose of alcohol
- Incorporates an extended hose from the top of the 1 gallon container to the trigger sprayer for hard to reach areas
- Double bagged packaged
- Gamma irradiated

Order#	Description	Quan/cs.
DEC-501	Hands-Free Back of Hand Activated Dispenser	1
DEC-100	Hands-Free Foot Pedal Activated Dispenser	1
200-P	1 Gallon Pump Spray Dispenser Sterile	4
300-T	1 Gallon Trigger Spray Dispenser Sterile	4

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

Technical Data File

DEC-PHENE®

STERILE PHARMACEUTICAL CLEAN ROOM FORMULA

DEC-PHENE is a sodium based, phosphate free phenolic synthetic germicidal detergent that is used where a broad spectrum disinfectant is required in moderate amounts of organic soil.

DEC-PHENE is:

- Filtered at 0.2 Microns
- Double-bagged packaged
- Gamma irradiated
- Strong enough to kill a broad spectrum of pathogenic and non-pathogenic bacteria
- Mild enough to have no harmful effect on the surface being disinfected
- Detergent that has efficacy performance that confirms to AOAC protocol testing at a use dilution of 1:128 in the presence of 5% blood serum at 20 degrees Celsius with an exposure time of 10 minutes
- Completely tested according to current USP compendium
- Delivered with lot specific Certificate of Analysis, and Sterility Report, Certificate of Irradiation
- Completely traceable
- Completely validated for sterility and shelf life

USES: DEC-PHENE is used for the decontamination of:

- Walls
- Ceilings
- Floors

Order#	Description	Quan/cs.
DP-01-E	DEC-PHENE Gallon Non-Sterile	4
DP-02-E	DEC-PHENE Gallon Sterile	4
DP-08-32Z-01-E	DEC-PHENE 32 oz 0.25 oz/gallon of water Sterile	12
DP-08-32Z-02-E	DEC-PHENE 32 oz 0.50 oz/gallon of water Sterile	12
DP-09-32Z-01-E	DEC-PHENE 32 oz 0.25 oz/gallon of water Non-sterile	12
DP-09-32Z-02-E	DEC-PHENE 32 oz 0.50 oz/gallon of water Non-sterile	12
DP-03-8Z-E	DEC-PHENE 8 oz. Sterile	24
DP-03-4Z-E	DEC-PHENE 4 oz. Sterile	24
DP-03-2Z-E	DEC-PHENE 2 oz. Sterile	24
DP-03-1Z-E	DEC-PHENE 1 oz. Sterile	24
DP-04-1Z-E	DEC-PHENE 1:128 use dilution SimpleMix® Sterile	4
DP-05-1Z-E	DEC-PHENE 1:128 use dilution SimpleMix® NonSterile	4
DP-06-16Z-01-E	DEC-PHENE 0.125 oz./16 oz. WFI Water SimpleMix® Sterile	12
DP-07-16Z-01-E	DEC-PHENE 0.125 oz./16 oz. WFI Water SimpleMix® NonSterile	12
DP-06-16Z-02-E	DEC-PHENE 0.250 oz./16 oz. WFI Water SimpleMix® Sterile	12
DP-07-16Z-02-E	DEC-PHENE 0.250 oz./16 oz. WFI Water SimpleMix® NonSterile	12

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

DEC-PHENE Product Validation
Technical Data File

DEC-PHASE®

STERILE PHARMACEUTICAL CLEAN ROOM FORMULA

DEC-PHASE is a potassium-based phenolic germicidal solution.

DEC-PHASE is:

- Filtered at 0.2 Microns
- Double-bagged packaged
- Gamma irradiated
- Used where a broad spectrum of disinfection is required in moderate amounts of organic soil
- Strong enough to kill a broad spectrum of pathogenic and non-pathogenic bacteria
- Mild enough to have no harmful effect on the surface being disinfected
- A phosphate free germicidal detergent that has efficacy performance which has been confirmed using AOAC protocol testing at a use dilution of 1:256 in the presence of 5% blood serum at 20 degrees Celsius with an exposure time of 10 minutes
- Completely tested according to current USP compendium
- Delivered with lot specific Certificate of Analysis and Sterility Report, Certificate of Irradiation
- Completely traceable
- Completely validated for sterility and shelf life

USES: DEC-PHASE is used for the decontamination of:

- Walls
- Ceilings
- Floors

Order#	Description	Quan/cs.
DPH-01-E	DEC-PHASE Gallons Non-Sterile	4
DPH-02-E	DEC-PHASE Gallons Sterile	4
DPH-08-32Z-01-E	DEC-PHASE 32 oz 0.125 oz/gallon of water Sterile	12
DPH-09-32Z-02-E	DEC-PHASE 32 oz 0.125 oz/gallon of water Non-Sterile	12
DPH-03-2Z-E	DEC-PHASE 2 oz. Sterile	24
DPH-04-1/2Z-E	DEC-PHASE 0.5/128 use dilution SimpleMix® Sterile	4
DPH-05-1/2Z-E	DEC-PHASE 0.5/128 use dilution SimpleMix® NonSterile	4
DPH-06-16Z-01-E	DEC-PHASE 0.0625 oz./16 oz. WFI water SimpleMix® Sterile	12
DPH-07-16Z-02-E	DEC-PHASE 0.0625 oz./16 oz. WFI water SimpleMix® NonSterile	12

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

DEC-PHASE Product Validation
Technical Data File

DEC-CYCLE®

STERILE PHARMACEUTICAL CLEAN ROOM FORMULA

DEC-CYCLE is a phosphate free germicidal detergent.

DEC-CYCLE is:

- Filtered at 0.2 Microns
- Double-bagged packaged
- Gamma irradiated
- A low pH phenolic, dilutable, hospital detergent effective in 10 minutes at 20 degrees Celsius in hard water up to 400 ppm (calculated as CaCO3) in the presence of 5% blood serum.
- Recommended for use in pharmaceutical, biotechnology, medical device manufacturing, hospitals and any health care institutions that are dedicated to controlling the hazards of cross contamination
- A multi-phenolic formula designed to clean, disinfect, and deodorize any washable inanimate surface
- Strong enough to kill a broad spectrum of pathogenic bacteria
- Mild enough to have no harmful effect on the surface being disinfected
- Completely tested according to current USP compendium
- Delivered with lot specific Certificate of Analysis and Sterility Report, Certificate of Irradiation
- Completely traceable
- Completely validated for sterility and shelf life

USES: DEC-CYCLE is for use on:

- Hard, inanimate surfaces in filling and gowning rooms
- General manufacturing areas
- Machinery tables
- Countertops
- Laminar flow benches
- Floors
- Walls
- Stainless steel
- Porcelain
- Glass
- Chrome

Order#	Description	Quan/cs.
DCY-01-E	DEC-CYCLE 1 Gallon Non-Sterile	4
DCY-02-E	DEC-CYCLE 1 Gallon Sterile	4
DCY-08-32Z-01-E	DEC-CYCLE 32 oz 0.125 oz/gallon of water Sterile	12
DCY-08-32Z-02-E	DEC-CYCLE 32 oz 0.25 oz/gallon of water Sterile	12
DCY-09-32Z-01-E	DEC-CYCLE 32 oz 0.125 oz/gallon of water Non-sterile	12
DCY-09-32Z-02-E	DEC-CYCLE 32 oz 0.25 oz/gallon of water Non-sterile	12
DCY-03-2Z-E	DEC-CYCLE 2 oz. Sterile	24
DCY-03-1Z-E	DEC-CYCLE 1 oz. Sterile	24
DCY-04-1/2Z-E	DEC-CYCLE 0.5/128 use dilution SimpleMix® Sterile	4
DCY-05-1/2Z-E	DEC-CYCLE 0.5/128 use dilution SimpleMix® NonSterile	4
DCY-06-16Z-01-E	DEC-CYCLE 0.0625 oz./16 oz. WFI water SimpleMix® Sterile	12
DCY-07-16Z-01-E	DEC-CYCLE 0.0625 oz./16 oz. WFI water SimpleMix® NonSterile	12
DCY-06-16Z-02-E	DEC-CYCLE 0.125 oz./16 oz. WFI water SimpleMix® Sterile	12
DCY-07-16Z-02-E	DEC-CYCLE 0.125 oz./16 oz. WFI water SimpleMix® NonSterile	12

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

DEC-CYCLE Product Validation
Technical Data File

PHENE-AHOL® SPRAY

SPRAY DISINFECTANT

PHENE-AHOL Spray is a combination of phenol and ethyl alcohol.

PHENE-AHOL is:

- Filtered at 0.2 Microns
- Double-bagged packaged
- Gamma irradiated
- Designed as a surface disinfectant and deodorant for moderate amounts of organic soil
- Quick-drying
- Leaves no oil, film or minimal residues
- Non-corrosive
- Strong enough to kill a broad spectrum of pathogenic and non-pathogenic bacteria
- Mild enough to have no harmful effect on the surface being disinfected
- A surface disinfectant that has efficacy performance which has been confirmed using AOAC protocol testing at a use dilution of 0.21% o-phenylphenol and 69.623% ethyl alcohol in the presence of 5% blood serum at 25 degrees Celsius at an exposure time of 10 minutes
- Completely tested according to current USP compendium
- Delivered with lot specific Certificate of Analysis and Sterility Report
- Completely traceable
- Completely validated for sterility and shelf life

USES: PHENE-AHOL Spray is used for decontamination of:

- Gloves
- Surfaces
- Carts
- Countertops
- Process lines
- Aseptic connections

Order#	Description	Quan/cs.
PA-02	PHENE-AHOL 16 oz. Sterile	12

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

Technical Data File

DEC-CLEAN®

STERILE CLEAN ROOM FORMULA

DEC-Clean is a cleaning agent designed to remove residues from disinfecting agents.

DEC-CLEAN is:

- Filtered at 0.2 Microns
- Double-bagged packaged
- Gamma irradiated
- One-step residue remover when diluted to 1:128 (1 ounce/1 gallon) of hard or soft water (400 ppm hard as CaCO3)
- Designed for washable, non-porous environmental surfaces
- Completely tested according to current USP compendium
- Delivered with lot specific Certificate of Analysis and Sterility Report
- Completely traceable
- Completely validated for sterility and shelf life

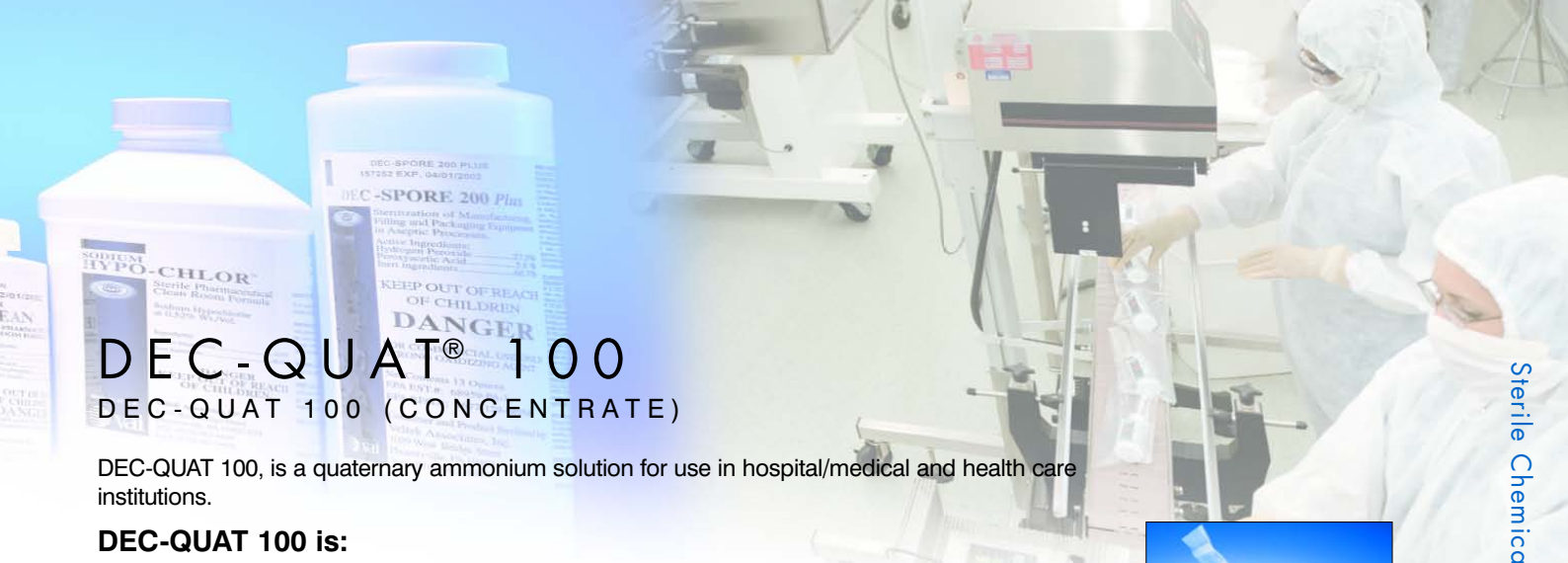
USES: DEC-CLEAN is used for:

- Walls
- Ceilings
- Floors
- Stainless items

Order#	Description	Quan/cs.
DC-01-E	DEC-Clean Gallons Non-Sterile	4
DC-02-E	DEC-Clean Gallons Sterile	4
DC-03-4Z-E	DEC-Clean 4 oz. Sterile	24
DC-04-1Z-E	DEC-Clean 1/128 use dilution SimpleMix® Sterile	4
DC-05-1Z-E	DEC-Clean 1/128 use dilution SimpleMix® NonSterile	4
DC-06-16Z-01-E	DEC-Clean 0.125 oz./16 oz. use dilution SimpleMix® Sterile	12
DC-07-16Z-01-E	DEC-Clean 0.125 oz./16 oz. use dilution SimpleMix® NonSterile	12

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

DEC-Clean Product Validation
Technical Data File



DEC-QUAT® 100

DEC-QUAT 100 (CONCENTRATE)

DEC-QUAT 100, is a quaternary ammonium solution for use in hospital/medical and health care institutions.

DEC-QUAT 100 is:

- Filtered at 0.2 Microns
- Double-bagged packaged
- Gamma irradiated
- Effective as a broad spectrum hospital disinfectant, fungicide, deodorizer, hard surface disinfectant, food and non-food contact sanitizer (USDA D2)
- Effective against Pseudomonas aeruginosa, Staphylococcus aureus and Salmonella choleraesuis
- Effective against Hepatitis B Virus (HBV) when contact time is 10 minutes at 1 ounce/1 gallon of water*
- A product that also kills Human Immunodeficiency Virus Type 1 (HIV) after 30 seconds contact time*
- A concentrate solution with active ingredients of 5% Alkyl (C14, 60%; C16, 30%; C12, 5%; C18, 5%) Dimethyl Benzyl Ammonium Chloride and 5% Akly (C12, 68%; C14, 32%) Dimethyl Ethylbenzyl Ammonium Chloride, and 90% Inert Ingredients
- Completely tested according to current USP compendium
- Delivered with lot specific Certificate of Analysis and Sterility Report
- Completely traceable
- Completely validated for sterility and shelf life

USES: DEC-QUAT 100 is used as a disinfectant on inanimate, hard, non-porous environmental surfaces such as:

- Walls
- Ceilings
- Floors
- Countertops

*SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATING AGAINST HIV-1 AND HBV OR SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS

Order#	Description	Quan/cs.
DQ100-01-E	DEC-QUAT 100 - 1 Gallon Concentrate Non-Sterile	4
DQ100-02-E	DEC-QUAT 100 - 1 Gallon Concentrate Sterile	4
DQ100-03-8Z-E	DEC-QUAT 100 - 8 oz. Concentrate Bottle Sterile	24
DQ100-04-2Z-E	DEC-QUAT 100 2/128 use dilution SimpleMix® Sterile	4
DQ100-05-2Z-E	DEC-QUAT 100 2/128 use dilution SimpleMix® NonSterile	4
DQ100-06-16Z-01-E	DEC-QUAT 100 0.250 oz./16 oz. WFI water SimpleMix® Sterile	12
DQ100-07-16Z-01-E	DEC-QUAT 100 0.250 oz./16 oz. WFI water SimpleMix® NonSterile	12

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

DEC-QUAT Product Validation
Technical Data File

HYPO-CHLOR®

STERILE CLEAN ROOM FORMULA

HYPO-CHLOR is a sterile sodium Hypochlorite solution.

HYPO-CHLOR is:

- Filtered at 0.2 Microns
- Double-bagged packaged
- Ready-to-use
- Available in premixed concentrations of 5.25%, 0.52% and 0.25%
- Formulated with USP Purified Water
- Completely tested according to current USP compendium
- Delivered with lot specific Certificate of Analysis and Sterility Report
- Completely traceable
- Completely validated for sterility and shelf life

USES: HYPO-CHLOR is used for:

- Walls
- Ceilings
- Floors
- Surfaces

Order#	Description	Quan/cs.
SHC-01-5.25	HYPO-CHLOR Gallons Non-Sterile @ 5.25%	4
SHC-02-5.25	HYPO-CHLOR Gallons Sterile @ 5.25%	4
SHC-02-0.52	HYPO-CHLOR Gallons Sterile @ 0.52%	4
SHC-02-0.25	HYPO-CHLOR Gallons Sterile @ 0.25%	4
SHC-16Z-5.25	HYPO-CHLOR 16 oz. Sterile @ 5.25%	12
SHC-16Z-0.52	HYPO-CHLOR 16 oz. Sterile @ 0.52%	12
SHC-16Z-0.25	HYPO-CHLOR 16 oz. Sterile @ 0.25%	12
SHC-13Z-5.25	HYPO-CHLOR 13 oz. Sterile @ 5.25%	12

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

HYPO-CHLOR Product Validation
Technical Data File

STERI-PEROX®

STERILE CLEAN ROOM FORMULA

STERI-PEROX is a sterile hydrogen peroxide solution.

STERI-PEROX is:

- Filtered at 0.2 Microns
- Double-bagged packaged
- Available in two premixed concentrations – 3% and 6%
- Formulated with USP Purified Water
- Ready-to-use
- Completely tested according to current USP compendium
- Delivered with lot specific Certificate of Analysis and Sterility Report
- Completely traceable
- Completely validated for sterility and shelf life

USES: STERI-PEROX is used for:

- Walls
- Ceilings
- Floors
- Surfaces

Order#	Description	Quan/cs.
SPER-01-3%	STERI-PEROX Gallons Non-Sterile @ 3%	4
SPER-01-6%	STERI-PEROX Gallons Non-Sterile @ 6%	4
SPER-02-3%	STERI-PEROX Gallons Sterile @ 3%	4
SPER-02-6%	STERI-PEROX Gallons Sterile @ 6%	4
SPER-16Z-3%	STERI-PEROX 16 oz. Sterile @ 3%	12
SPER-16Z-6%	STERI-PEROX 16 oz. Sterile @ 6%	12
SPER-WFI-55-3%	STERI-PEROX 55 Gallon Sterile @ 3%	1

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

STERI-PEROX Product Validation
Technical Data File

DEC-SPORE® 200 *PLUS*

STERILE CLEAN ROOM FORMULA

DEC-SPORE 200 Plus is a peracetic acid and hydrogen peroxide solution that can be used as either a steriliant or disinfectant.

DEC-SPORE 200 Plus is:

- Filtered at 0.2 Microns
- Gamma irradiated
- Designed for the sterilization of manufacturing, packaging and filling equipment in aseptic processes.
- Confirmed by AOAC protocol testing at a dilution of 5% (6.4 ounces/128 ounces) in hard or soft water (500 ppm as CaCO3) for sterilization
  - Suggested to be exposed to the surface for a minimum exposure time based on the temperature of the solution:
    - 68 degrees, 6 hours
    - 122 degrees, 20 minutes
    - 176 degrees, 5 minutes
- Confirmed by AOAC protocol testing at a dilution of 0.3% (0.394 ounces/1 gallon) in hard or soft water for disinfection
  - Suggested to be exposed to the surface for 10 minutes at 20 degrees Celsius in the presence of 5% blood serum and soap film on a non-porous surface
- Completely tested according to current USP compendium
- Delivered with lot specific Certificate of Analysis and Sterility Report
- Completely traceable
- Completely validated for sterility and shelf life

USES: DEC-SPORE 200 Plus is used for:

• Walls • Ceilings • Floors • Surfaces

Order#	Description	Quan/cs.
DS200-01A-E	DEC-SPORE 200 Plus 1-Gallon Non-Sterile	4
DS200-02A-E	DEC-SPORE 200 Plus 1-Gallon Sterile	4
DS200-08-32Z-01-E	DEC-SPORE 200 Plus 32 oz 0.125 oz/gallon of water Sterile	12
DS200-08-32Z-02-E	DEC-SPORE 200 Plus 32 oz 1.60 oz/gallon of water Sterile	12
DS200-09-32Z-01-E	DEC-SPORE 200 Plus 32 oz 0.125 oz/gallon of water Non-sterile	12
DS200-09-32Z-02-E	DEC-SPORE 200 Plus 32 oz 1.60 oz/gallon of water Non-sterile	12
DS200-03-13ZA-E	DEC-SPORE 200 Plus 13oz. Sterile *(Unit Dose sterilant w/2 gal of water)*	12
DS200-03-2ZA-E	DEC-SPORE 200 Plus 2oz. Sterile *(Unit Dose disinfectant w/4 gal of water)*	24
DS200-03-1ZA-E	DEC-SPORE 200 Plus 1 oz. Sterile	24
DS200-04-1/2ZA-E	DEC-SPORE 200 Plus 0.5/128 use dilution SimpleMix® Sterile	4
DS200-05-1/2ZA-E	DEC-SPORE 200 Plus 0.5/128 use dilution SimpleMix® NonSterile	4
DS200-04A-E	DEC-SPORE 200 Plus 6.4/128 use dilution SimpleMix® Sterile	4
DS200-05A-E	DEC-SPORE 200 Plus 6.4/128 use dilution SimpleMix® NonSterile	4
DS200-06-16Z-01-E	DEC-SPORE 200 Plus 0.8 oz./16 oz. WFI water SimpleMix® Sterile	12
DS200-07-16Z-01-E	DEC-SPORE 200 Plus 0.8 oz./16 oz. WFI water SimpleMix® NonSterile	12
DS200-06-16Z-02-E	DEC-SPORE 200 Plus 0.0625 oz./16 oz. WFI water SimpleMix® Sterile	12
DS200-07-16Z-02-E	DEC-SPORE 200 Plus 0.0625 oz./16 oz. WFI water SimpleMix® NonSterile	12

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

DEC-SPORE 200 Plus Product Validation
Technical Data File

STERI-WATER®

STERILE CLEAN ROOM FORMULA

STERI-WATER is a sterile USP Purified Water.

VAI WFI QUALITY WATER is:

- Filtered at 0.2 Microns
- Double-bagged packaged
- Gamma irradiated
- Ready-to-use
- Completely tested according to current USP compendium
- Delivered with lot specific Certificate of Analysis and Sterility Report
- Completely traceable
- Completely validated for sterility and shelf life

USES: STERI-WATER is used where the availability of a quality water grade is necessary in:

- Chemical formulation
- Cleaning
- Rinsing

Order#	Description	Quan/cs.
STWA-01	STERI-WATER Gallons Non-Sterile	4
STWA-02	STERI-WATER Gallons Sterile	4
STWA-16Z	STERI-WATER 16 oz. Sterile	12
STWA-2G	STERI-WATER 2 Gallons Sterile	2
STWA-5G	STERI-WATER 5 Gallons Sterile	1

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

STERI-WATER Product Validation
Technical Data File

VAI WFI QUALITY WATER®

FOR STERILE DISINFECTANT DILUTIONS IN CLEAN ROOM OPERATIONS

VAI WFI QUALITY WATER is a high quality water produced from our validated WFI water system.

VAI WFI QUALITY WATER is:

- Filtered at 0.2 Microns
- Double-bagged packaged
- Gamma irradiated
- Manufactured in a GMP, Class 100 (ISO 5, Grade A) area
- An excellent choice for dilution of disinfectant concentrates to a use-dilution mixture
- Tested for assay, sterility and endotoxin levels
- Completely tested according to current USP compendium
- Delivered with lot specific Certificate of Analysis and Sterility Report
- Completely traceable
- Completely validated for sterility and shelf life

USES: VAI WFI QUALITY WATER is:

- For disinfectant preparation and dilution
- Not for parenteral administration

Order#	Description	Quan/cs.
VAIWFI-16Z	VAI WFI Quality Water 16 oz Trigger Spray Container Sterile	12
VAIWFI-1G	VAI WFI Quality Water 1 Gallon Container Sterile	4
VAIWFI-2G	VAI WFI Quality Water 2 Gallon Container Sterile	2
VAIWFI-200L	VAI WFI Quality Water 200 Liter VAI-Carboy Bag Sterile	1

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

Technical Data File

STERI-BUFFER® 90&99

STERILE PHOSPHATE BUFFER
PH 7.2 ± 0.2 MADE WITH USP WATER FOR INJECTION

STERI-BUFFER, 90 & 99 are a sterile phosphate buffered to a pH of 7.2 ± 0.2.

STERI-BUFFER is:

- Filled in easy-open and close wide-mouth bottles
- Filtered at 0.2 microns
- Terminally sterilized through a validated cycle at a SAL level of 10^{-6} to assure sterility
- Lot sterility tested per current USP compendium
- Delivered with a Certificate of Analysis and Certificate of Sterility
- Sealed with a “no-tamper” strip that is broken once the bottle is opened
- Filled in a Class 100 clean room
- Validated for sterility and shelf life of 2 years
- Filled in bottles that are scaled on 4 sides for easy measurement

USES: VAI WFI QUALITY WATER is:

- For disinfectant preparation and dilution
- Not for parenteral administration

Order#	Description	Quan/cs.
SB100-90	Steri-Buffer 90 - 90 mL Sodium Phosphate Buffer	72
SB100-99	Steri-Buffer 99 - 99 mL Sodium Phosphate Buffer	72

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

Steri-Buffer Product Validation
Technical Data File

STERI-OIL® 200

STERILE CLEAN ROOM FORMULA

STERI-OIL is a sterile mineral oil lubricant for use in the aseptic manufacturing area.

STERI-OIL is:

- Filtered at 0.2 Microns
- Double-bagged packaged
- Gamma irradiated
- A sterile USP grade mineral oil lubricant
- Heavy in consistency providing lubrication and preventing metal to metal contact
- Able to withstand high friction without displacement
- Able to reduce metal fatigue
- Completely tested according to current USP compendium
- Delivered with lot specific Certificate of Analysis, and Sterility Report
- Completely traceable
- Completely validated for sterility and shelf life

USES: STERI-OIL:

- Reduces items from sticking
- Penetrates
- Lubricates mechanisms
- Used for moisture displacement

Order#	Description	Quan/cs.
SO-200-A1Z	STERI-OIL 200 1 oz. Dropper Sterile	250

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

Steri-Oil Product Validation
Technical Data File

STERI-SILICON®

STERILE CLEAN ROOM FORMULA

STERI-SILICON is a sterile lubricant and releasing spray.

STERI-SILICON is:

- Filtered at 0.2 Microns
- Double-bagged packaged
- Gamma irradiated
- A USDA Approved (H2) sterile lubricant for use in the aseptic manufacturing area
- Colorless
- Inert
- Temperature stable from –40 degrees to 500 degrees Fahrenheit
- Completely tested according to current USP compendium
- Delivered with lot specific Certificate of Analysis and Sterility Report
- Completely traceable
- Completely validated for sterility and shelf life

USES: STERI-SILICON is used to speed the process of heat sealing, packaging and process machinery.

Order#	Description	Quan/cs.
SSIL-02	STERI-SILICON, 8 oz. Aerosol Spray Sterile	24

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

Steri-Silicon Product Validation
Technical Data File

STEEL-BRIGHT® AND DAS-WIPE® 100

CLEAN ROOM FORMULA

STEEL-BRIGHT sterile stainless steel cleaner addresses the use of a sterile cleaner within the aseptic manufacturing area.

STEEL-BRIGHT is:

- Filtered at 0.2 Microns
- Double-bagged packaged
- Gamma irradiated
- Used for removal of chemical residues, spotting and staining on stainless steel surfaces without leaving a powdery residue
- Emulsion based USDA Authorized (A7) cleaner that will not rainbow or accumulate to a heavy build up
- Completely tested according to current USP compendium
- Delivered with lot specific Certificate of Analysis and Sterility Report
- Completely traceable
- Completely validated for sterility and shelf life

USES: STEEL-BRIGHT is used for the cleaning of:

- Stainless steel
- Chrome
- Brass
- Aluminum
- Copper

DAS-WIPE 100 is a saturated 12 inch x 12 inch flat wipe.

DAS-WIPE 100 is:

- Saturated with our stainless steel cleaner and lubricant with low remaining residues that can be removed with an IPA wipedown
- Filtered at 0.2 Microns
- Double-bagged packaged
- Gamma irradiated
- Completely tested according to current USP compendium
- Delivered with lot specific Certificate of Analysis and Sterility Report
- Completely traceable
- Completely validated for sterility and shelf life
- Designed to replace silicon on turntables, process lines and as a general lubricant
- Designed to assure bottles do not stick during movement towards a critical fill site
- Made of a polyester blend inherently low in particulate and shedding features

USES: DAS-WIPE 100 is used for the cleaning of Stainless Steel

Order#	Description	Quan/cs.
SB-02	STEEL-BRIGHT 8oz. Aerosol Spray Sterile	24
SBW-12x12-S	STEEL-BRIGHT Wipes Sterile 12"x12"	100
DW100-12x12-S	DAS-Wipe 100 Wipes Sterile 12"x12"	100

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

Steel Bright Product Validation
Technical Data File

DEC-GLASS®

DEC-GLASS is designed for pharmaceutical and biotechnology operations that demand a sterile glass and plexiglass cleaner capable of the removal of residues from disinfecting agents.

DEC-GLASS is:

- Filtered at 0.2 Microns
- Double-bagged packaged
- Gamma irradiated
- Ready-to-use residue remover for glass and plexiglass
- Formulated with Purified Water
- Designed for all washable environmental surfaces
- Removes noticeable and unnoticeable residues, smudges, oils and dirt buildup
- Available in 16 ounce trigger spray containers
- Completely tested according to current USP compendium
- Delivered with lot specific Certificate of Analysis and Sterility Report
- Completely traceable
- Completely validated for sterility and shelf life

USES: DEC-GLASS is used for the cleaning of:

- Glass
- Plexiglass
- Surfaces

Order#	Description	Quan/cs.
DG-03-16Z-E	DEC-Glass, Sterile 16 oz.	12

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

DEC-Glass Product Validation
Technical Data File

DEC-SOAP®

DEC-SOAP, is a gentle formulation that cleans and moisturizes hands.

DEC-SOAP:

- Is a antibacterial formula designed to protect against cross-contamination
- Contains Triclosan that kills bacteria on contact
- Effectively removes dirt from hands

USES: DEC-SOAP is an effective killing agent for:

- Staphylococcus Aureus
- Methicillin Resistant Staphylococcus Aureus (MRSA)
- Staphylococcus Epidermidis
- Streptococcus Pyogenes

Order#	Description	Quan/cs.
DSOAP-01-E	DEC-SOAP, 32 oz. bag for use with Asepti-Cleanse® unit	8

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

Technical Data File

PRODUCT	DESCRIPTION
Process2Clean1	Alkaline Detergent
Process2Clean2	Acidic Based Detergent
Process2Clean3	Hydroxyacetic Acid Detergent
Process2Clean4	General Purpose Cleaning Detergent
Process2Clean5	Neutral PH Cleaning Additive
Process2Clean6	Chlorinated Alkaline Cleaning Detergent

WELCOME TO PROCESS2CLEAN

Process2Clean products have been specifically designed for **critical clean in place applications**. In this venue, the appropriate use of clean in place cleaners warrants two concerns. The first concern relates to the ability of the specific detergent to remove existent product residues that may exist in either open or closed processes manufacturing equipment and vessels. The second concern is the ability to rinse free the product residue, any contamination that has entered and the clean in place detergent itself to assure that such surfaces are clean prior to the formulation and manufacturing of a new lot of product. In short, if one introduces contamination, may it be viable, non-viable or residual, then one must assure its removal. To address the lowering of contamination, **Process2Clean** products are available in both a sterile (filtered at 0.2 microns and aseptically filtered) and non-sterile packaging configurations. The sterile versions are ultra clean and assure that less contamination is introduced to the system. Thus, sterilize in place (SIP) systems have less work to do.

Process2Clean products have been engineered to effectively remove a multitude of product residues. All products are formulated under the highest quality standards in Veltek Associates, Inc.'s GMP manufacturing facility.

PROCESS 2 CLEAN

FOR CRITICAL CLEAN IN PLACE APPLICATIONS

one

ALKALINE DETERGENT

610-644-8335

ALKALINE DETERGENT
Available in Sterile and Non-Sterile Formulations

DESIGNED SPECIFICALLY FOR CRITICAL CLEAN IN PLACE APPLICATIONS

For use on:

Processing Equipment
Process Tanks and Vessels
Bioreactors
Blending Equipment
Tablet Presses
Laboratory and Production Glassware Washing
Production and Testing Component Parts
Ultrasonic Cleaning

For use in the following facilities:

Pharmaceutical
Biotechnology
Research and Development
Cosmetics
Medical Device
Food & Beverage

What is Important?

The appropriate use of clean in place cleaners warrants two concerns. The first concern relates to the ability of the specific detergent to remove existent product residues that may exist in either open or closed processes manufacturing equipment and vessels. The second concern is the ability to rinse free the product residue, any contamination that has entered and the clean in place detergent itself to assure that such surfaces are clean prior to the formulation and manufacturing of a new lot of product. In short, if one introduces contamination, may it be viable, non-viable or residual, then one must assure its removal. Thus **Process2Clean 1** is available in both a sterile (filtered at 0.2 microns and aseptically filtered) and non-sterile packaging configurations. The sterile versions are ultra clean and assure that less contamination is introduced to the system. Thus, sterilize in place (SIP) systems have less work to do.

Process2Clean 1 is a high performance concentrated liquid alkaline cleaning agent designed specifically for clean in place requirements in the pharmaceutical, biotechnology, cosmetic, medical device, food and beverage industries. **Process2Clean 1** is formulated with potassium hydroxide, surfactants, chelating agents, and other critically essential cleaning ingredients. The wide array of components provides a stabilized formula that is capable of cleaning a multitude of product and non-product contact surfaces. The formulation is Veltek's most effective broad spectrum cleaning agent that is capable of removing a wide array of residues. This product is extremely effective in removing residues that include a wide array of proteins, excipients, fine chemicals, silicones, oils, petrolatum, polymers and most all types of organics.

PROCESS2CLEAN
FOR CRITICAL CLEAN IN PLACE APPLICATIONS

Process2Clean 1 is a low foaming cleaning agent (at all temperatures) and has enhanced cleaning and the ability to rinse free from systems. The phosphate free agent can be used in both CIP and COP applications. An extensive validation support package is available and is complimented with Veltek Associates, Inc.'s CORE (Critical Ongoing Residue Evaluation) Laboratory that can assist with specialized testing to meet your specific needs.

Feature	Benefit
A low foaming, phosphate free formulated alkaline cleaner	This product cleans with a multitude of chemistries safer than general solvents or commodity chemicals. It is extremely effective in removing residues that include a wide array of proteins, excipients, fine chemicals, silicones, oils, petrolatum, polymers and most all types of organics.
Sterile and Non-Sterile Versions	At times, firms are concerned with not only the ability of the CIP product to clean and rinse free but also what has been introduced to the system by the CIP product. The sterile versions are filtered at 0.2 microns in a GMP Class 100 manufacturing area into presterilized containers. Each lot is tested for sterility via current USP compendium. The sterile version eliminates the concern for unwanted particulates, microorganisms and pyrogens that may be introduced through the CIP chemical.
Specific and non-specific methods to detect cleaning agent residues. The methods include HPLC, TOC, IC, IR, Freon and others	These methods can assist in the validation process of end users by eliminating the need for customers to develop their own analytical methods. The "CORE" System also develops specific methods unique to the customer's needs.
Complete Rinsing of Cleaning Agent Ingredients	The formula is designed to easily rinse free from product surfaces. Water rinse time period and volume is minimal.
All products are manufactured and tested from beginning to end in a FDA and EPA registered manufacturing facility.	Meets the highest standard in manufacturing and processing.
Lot Specific Documentation Package	All product is lot traceable and delivered each time with the lot specific certification. All lots are traced through the master batch records.
High Level of Quality	All products are made in controlled environments that include Class 100, Class 10,000 and Class 100,000. This assures the highest level of quality and cleanliness of the final product.
Phosphate Free Detergent	Environment Safe
Use concentrations range from 1% to 8%.	Dependent upon the requirements of the soil load to be cleaned varying concentrations are used to efficiently clean the existent residues in the shortest time period.

PHYSICAL PROPERTIES

Appearance	Colorless Clear Liquid
Odor	Slight Chemical
Specific Gravity	1.25
pH - 1% solution (normal)	12.5
Solubility	Complete
Foaming	Minimal due to product enhancements
Rinsing	Excellent

EUROPEAN ORDERING INFORMATION

Order Number	Description	Container Size	Qty. per case
PC-1-55G-01-E	Process2Clean 1 Non-Sterile	208.197 Liters	1
PC-1-55G-02-E	Process2Clean 1 Sterile	208.197 Liters	1
PC-1-5G-01-E	Process2Clean 1 Non-Sterile	18.927 Liters	1
PC-1-5G-02-E	Process2Clean 1 Sterile	18.927 Liters	1
PC-1-1G-01-E	Process2Clean 1 Non-Sterile	3.785412 Liters	4
PC-1-1G-02-E	Process2Clean 1 Sterile	3.785412 Liters	4

ADDITIONAL DOCUMENTATION PACKAGES (Available Upon Request)

- Sample Lot Specific Certification
- Technical Product PDF File
- Material Safety Data Sheet
- Product Cleaning Validation Report
- Product Sterility Validation Report
- CORE Product Analysis

PROCESS 2 CLEAN

FOR CRITICAL CLEAN IN PLACE APPLICATIONS

two

ACIDIC BASED DETERGENT

610-644-8335

PROCESS2CLEAN
FOR CRITICAL CLEAN IN PLACE APPLICATIONS

ACIDIC BASED DETERGENT

Available in Sterile and Non-Sterile Formulations

DESIGNED SPECIFICALLY FOR CRITICAL CLEAN IN PLACE APPLICATIONS

For use on:

Processing Equipment
Process Tanks and Vessels
Bioreactors
Derouging and Passivation Processes
Blending Equipment
Tablet Presses
Laboratory and Production Glassware Washing
Production and Testing Component Parts
Ultrasonic Cleaning
Animal Cages
Antacid Cleaning Applications

For use in the following facilities:

Pharmaceutical
Biotechnology
Research and Development
Cosmetics
Medical Device
Food & Beverage
Animal

What is Important?

The appropriate use of clean in place cleaners warrants two concerns. The first concern relates to the ability of the specific detergent to remove existent product residues that may exist in either open or closed processes manufacturing equipment and vessels. The second concern is the ability to rinse free the product residue, any contamination that has entered and the clean in place detergent itself to assure that such surfaces are clean prior to the formulation and manufacturing of a new lot of product. In short, if one introduces contamination, may it be viable, non-viable or residual, then one must assure its removal. Thus **Process2Clean 2** is available in both a sterile (filtered at 0.2 microns and aseptically filtered) and non-sterile packaging configurations. The sterile versions are ultra clean and assure that less contamination is introduced to the system. Thus, sterilize in place (SIP) systems have less work to do.

Process2Clean 2 is a high performance concentrated liquid acid cleaning agent designed specifically for clean in place requirements in the pharmaceutical, biotechnology, cosmetic, medical device, food and beverage industries. **Process2Clean 2** is formulated with phosphoric acid, surfactants, chelating agents, and other critically essential cleaning ingredients. The wide array of components provides a stabilized formula that is capable of cleaning a multitude of product and non-product contact surfaces. The formulation is Veltek's most effective acid cleaning agent that is capable of removing a wide array of residues. This product is extremely effective in removing residues that include a wide array of inorganic salts, scales, particulate carbon, urine scales, proteins, excipients, fine chemicals, silicones, oils, petrolatum, polymers and most all types of organics. This product is especially effective on antacid formulations and animal urine (in polycarbonate, stainless and other caging materials). Routine use of this product reduces corrosion, pitting and rusting.

Process2Clean 2 is a low foaming cleaning agent (at all temperatures) and has enhanced cleaning and the ability to rinse free from systems. The phosphate free agent can be used in both CIP and COP applications. An extensive validation support package is available and is complimented with Veltek Associates, Inc.'s CORE (Critical Ongoing Residue Evaluation) Laboratory that can assist with specialized testing to meet your specific needs.

Feature	Benefit
A low foaming, phosphate free formulated acid cleaner	This product cleans with a multitude of chemistries safer than general solvents or commodity chemicals. It is extremely effective in removing residues that include a wide array of proteins, excipients, fine chemicals, silicones, oils, petrolatum, polymers and most all types of organics.
Sterile and Non-Sterile Versions	At times, firms are concerned with not only the ability of the CIP product to clean and rinse free but also what has been introduced to the system by the CIP product. The sterile versions are filtered at 0.2 microns in a GMP Class 100 manufacturing area into presterilized containers. Each lot is tested for sterility via current USP compendium. The sterile version eliminates the concern for unwanted particulates, microorganisms and pyrogens that may be introduced through the CIP chemical.
Specific and non-specific methods to detect cleaning agent residues. The methods include HPLC, TOC, IC, IR, Freon and others	These methods can assist in the validation process of end users by eliminating the need for customers to develop their own analytical methods. The "CORE" System also develops specific methods unique to the customer's needs.
Complete Rinsing of Cleaning Agent Ingredients	The formula is designed to easily rinse free from product surfaces. Water rinse time period and volume is minimal.
All products are manufactured and tested from beginning to end in a FDA, and EPA registered manufacturing facility.	Meets the highest standard in manufacturing and processing.
Lot Specific Documentation Package	All product is lot traceable and delivered each time with the lot specific certification. All lots are traced through the master batch records.
High Level of Quality	All products are made in controlled environments that include Class 100, Class 10,000 and Class 100,000. This assures the highest level of quality and cleanliness of the final product.
Phosphate Free Detergent	Environment Safe
Use concentrations range from 1% to 5%.	Dependent upon the requirements of the soil load to be cleaned varying concentrations are used to efficiently clean the existent residues in the shortest time period.

PHYSICAL PROPERTIES

Appearance	Colorless Clear Liquid
Odor	Slight Chemical
Specific Gravity	1.25
pH - 1% solution (normal)	2.0
Solubility	Complete
Foaming	Minimal due to product enhancements
Rinsing	Excellent

EUROPEAN ORDERING INFORMATION

Order Number	Description	Container Size	Qty. per case
PC-2-55G-01-E	Process2Clean 2 Non-Sterile	208.197 Liters	1
PC-2-55G-02-E	Process2Clean 2 Sterile	208.197 Liters	1
PC-22-5G-01-E	Process2Clean 2 Non-Sterile	18.927 Liters	1
PC-2-5G-02-E	Process2Clean 2 Sterile	18.927 Liters	1
PC-2-1G-01-E	Process2Clean 2 Non-Sterile	3.785412 Liters	4
PC-2-1G-02-E	Process2Clean 2 Sterile	3.785412 Liters	4

ADDITIONAL DOCUMENTATION PACKAGES (Available Upon Request)

- Sample Lot Specific Certification
- Technical Product PDF File
- Material Safety Data Sheet
- Product Cleaning Validation Report
- Product Sterility Validation Report
- CORE Product Analysis

PROCESS 2 CLEAN

FOR CRITICAL CLEAN IN PLACE APPLICATIONS

three

HYDROXYACETIC ACID DETERGENT

610-644-8335

HYDROXYACETIC ACID DETERGENT
Available in Sterile and Non-Sterile Formulations

DESIGNED SPECIFICALLY FOR CRITICAL CLEAN IN PLACE APPLICATIONS

For use on:

Processing Equipment
Process Tanks and Vessels
Bioreactors
Derouging and Passivation Processes
High Pressure Spray Applications
Blending Equipment
Tablet Presses
Laboratory and Production Glassware Washing
Production and Testing Component Parts
Ultrasonic Cleaning
Animal Cages
Stainless Steel

For use in the following facilities:

Pharmaceutical
Biotechnology
Research and Development
Cosmetics
Medical Device
Food & Beverage
Animal

What is Important?

The appropriate use of clean in place cleaners warrants two concerns. The first concern relates to the ability of the specific detergent to remove existent product residues that may exist in either open or closed processes manufacturing equipment and vessels. The second concern is the ability to rinse free the product residue, any contamination that has entered and the clean in place detergent itself to assure that such surfaces are clean prior to the formulation and manufacturing of a new lot of product. In short, if one introduces contamination, may it be viable, non-viable or residual, then one must assure its removal. Thus **Process2Clean 3** is available in both a sterile (filtered at 0.2 microns and aseptically filtered) and non-sterile packaging configurations. The sterile versions are ultra clean and assure that less contamination is introduced to the system. Thus, sterilize in place (SIP) systems have less work to do.

Process2Clean 3 is a high performance concentrated hydroxyacetic acid cleaner/descaler liquid cleaning agent designed specifically for clean in place requirements in the pharmaceutical, biotechnology, cosmetic, medical device, food and beverage industries. Process2Clean 3 is formulated with phosphoric acid, surfactants, chelating agents, and other critically essential cleaning ingredients. The wide array of components provides a stabilized formula that is capable of cleaning a multitude of product and non-product contact surfaces. The formulation is one of Veltek's most effective acid cleaning agents that is capable of removing a wide array of residues. This product was designed specifically for use in high pressure cleaning applications. The product is extremely effective in removing residues that include a wide array of inorganic salts, scales, particulate carbon, urine scales, proteins, excipients, fine chemicals, silicones, oils, petrolatum, polymers and most all types of organics. This product is especially effective on antacid formulations and animal urine (in polycarbonate, stainless and other caging materials). Routine use of this product is helpful in removal of free metals and reduces corrosion, pitting and rusting.

PROCESS2CLEAN
FOR CRITICAL CLEAN IN PLACE APPLICATIONS

Process2Clean 3 is a low foaming cleaning agent (at all temperatures) and has enhanced cleaning and the ability to rinse free from systems. The phosphate free agent can be used in both CIP and COP applications. An extensive validation support package is available and is complimented with Veltek Associates, Inc.'s CORE (Critical Ongoing Residue Evaluation) Laboratory that can assist with specialized testing to meet your specific needs.

Feature	Benefit
A low foaming, phosphate free formulated acid cleaner	This product cleans with a multitude of chemistries safer than general solvents or commodity chemicals. It is extremely effective in removing residues that include a wide array of proteins, excipients, fine chemicals, silicones, oils, petrolatum, polymers and most all types of organics.
Sterile and Non-Sterile Versions	At times, firms are concerned with not only the ability of the CIP product to clean and rinse free but also what has been introduced to the system by the CIP product. The sterile versions are filtered at 0.2 microns in a GMP Class 100 manufacturing area into presterilized containers. Each lot is tested for sterility via current USP compendium. The sterile version eliminates the concern for unwanted particulates, microorganisms and pyrogens that may be introduced through the CIP chemical.
Specific and non-specific methods to detect cleaning agent residues. The methods include HPLC, TOC, IC, IR, Freon and others	These methods can assist in the validation process of end users by eliminating the need for customers to develop their own analytical methods. The "CORE" System also develops specific methods unique to the customer's needs.
Complete Rinsing of Cleaning Agent Ingredients	The formula is designed to easily rinse free from product surfaces. Water rinse time period and volume is minimal.
All products are manufactured and tested from beginning to end in a FDA, and EPA registered manufacturing facility.	Meets the highest standard in manufacturing and processing.
Lot Specific Documentation Package	All product is lot traceable and delivered each time with the lot specific certification. All lots are traced through the master batch records.
High Level of Quality	All products are made in controlled environments that include Class 100, Class 10,000 and Class 100,000. This assures the highest level of quality and cleanliness of the final product.
Phosphate Free Detergent	Environment Safe
Use concentrations range from 2% to 5%.	Dependent upon the requirements of the soil load to be cleaned varying concentrations are used to efficiently clean the existent residues in the shortest time period.

PHYSICAL PROPERTIES

Appearance	Colorless Clear Liquid
Odor	Slight Chemical
Specific Gravity	1.12
pH - 1% solution (normal)	2.8
Solubility	Complete
Foaming	Minimal due to product enhancements
Rinsing	Excellent

EUROPEAN ORDERING INFORMATION

Order Number	Description	Container Size	Qty. per case
PC-3-55G-01-E	Process2Clean 3 Non-Sterile	208.197 Liters	1
PC-3-55G-02-E	Process2Clean 3 Sterile	208.197 Liters	1
PC-3-5G-01-E	Process2Clean 3 Non-Sterile	18.927 Liters	1
PC-3-5G-02-E	Process2Clean 3 Sterile	18.927 Liters	1
PC-3-1G-01-E	Process2Clean 3 Non-Sterile	3.785412 Liters	4
PC-3-1G-02-E	Process2Clean 3 Sterile	3.785412 Liters	4

ADDITIONAL DOCUMENTATION PACKAGES (Available Upon Request)

- Sample Lot Specific Certification
- Technical Product PDF File
- Material Safety Data Sheet
- Product Cleaning Validation Report
- Product Sterility Validation Report
- CORE Product Analysis

PROCESS 2 CLEAN

FOR CRITICAL CLEAN IN PLACE APPLICATIONS

four

GENERAL PURPOSE CLEANING DETERGENT

610-644-8335

PROCESS2CLEAN
FOR CRITICAL CLEAN IN PLACE APPLICATIONS

GENERAL PURPOSE CLEANING DETERGENT
Available in Sterile and Non-Sterile Formulations

DESIGNED SPECIFICALLY FOR CRITICAL CLEAN IN PLACE APPLICATIONS

For use on:

Processing Equipment
Process Tanks and Vessels
Bioreactors
Blending Equipment
Tablet Presses
Production and Testing Component Parts
Laboratory Glassware
Ultrasonic Cleaning
Animal Cages
Stainless Steel

For use in the following facilities:

Pharmaceutical
Biotechnology
Research and Development
Cosmetics
Medical Device
Food & Beverage

What is Important?

The appropriate use of clean in place cleaners warrants two concerns. The first concern relates to the ability of the specific detergent to remove existent product residues that may exist in either open or closed processes manufacturing equipment and vessels. The second concern is the ability to rinse free the product residue, any contamination that has entered and the clean in place detergent itself to assure that such surfaces are clean prior to the formulation and manufacturing of a new lot of product. In short, if one introduces contamination, may it be viable, non-viable or residual, then one must assure its removal. Thus **Process2Clean 4** is available in both a sterile (filtered at 0.2 microns and aseptically filtered) and non-sterile packaging configurations. The sterile versions are ultra clean and assure that less contamination is introduced to the system. Thus, sterilize in place (SIP) systems have less work to do.

Process2Clean 4 is a high performance concentrated liquid cleaning agent designed specifically for clean in place requirements in the pharmaceutical, biotechnology, cosmetic, medical device, food and beverage industries. **Process2Clean 4** is designed for use in low-energy agitated immersion systems, pressure spray or foam applications, or manual washing application. It is extremely effective in cleaning ointments, creams, oils, waxes, greases, petrolatum-based products. **Process2Clean 4** can be used as a stand alone cleaner or as an additive to alkaline cleaners to enhance their cleaning capabilities. The wide array of components provides a stabilized formula that is capable of cleaning a multitude of product and non-product contact surfaces. The formulation is one of Veltek's most effective cleaning agents that is capable of specifically removing oils, waxes, creams and polymers.

PROCESS2CLEAN
FOR CRITICAL CLEAN IN PLACE APPLICATIONS

Process2Clean 4 is an enhanced cleaning with the ability to rinse free from systems. The phosphate free agent can be used in both CIP and COP applications. An extensive validation support package is available and is complimented with Veltek Associates, Inc.'s CORE (Critical Ongoing Residue Evaluation) Laboratory that can assist with specialized testing to meet your specific needs.

Feature	Benefit
Formulated cleaner designed specifically to address waxes, oils, creams and other polymers.	This product cleans with a multitude of chemistries safer than general solvents or commodity chemicals. It is extremely effective in removing residues that include a wide array of proteins, excipients, fine chemicals, silicones, oils, petrolatum, polymers and most all types of organics.
Sterile and Non-Sterile Versions	At times, firms are concerned with not only the ability of the CIP product to clean and rinse free but also what has been introduced to the system by the CIP product. The sterile versions are filtered at 0.2 microns in a GMP Class 100 manufacturing area into presterilized containers. Each lot is tested for sterility via current USP compendium. The sterile version eliminates the concern for unwanted particulates, microorganisms and pyrogens that may be introduced through the CIP chemical.
Specific and non-specific methods to detect cleaning agent residues. The methods include HPLC, TOC, IC, IR, Freon and others	These methods can assist in the validation process of end users by eliminating the need for customers to develop their own analytical methods. The "CORE" System also develops specific methods unique to the customer's needs.
Complete Rinsing of Cleaning Agent Ingredients	The formula is designed to easily rinse free from product surfaces. Water rinse time period and volume is minimal.
All products are manufactured and tested from beginning to end in a FDA and EPA registered manufacturing facility.	Meets the highest standard in manufacturing and processing.
Lot Specific Documentation Package	All product is lot traceable and delivered each time with the lot specific certification. All lots are traced through the master batch records.
High Level of Quality	All products are made in controlled environments that include Class 100, Class 10,000 and Class 100,000. This assures the highest level of quality and cleanliness of the final product.
Use concentrations range from 2% to 5%.	Dependent upon the requirements of the soil load to be cleaned varying concentrations are used to efficiently clean the existent residues in the shortest time period. The product is highly concentrated so less chemical agent needs to be used.

PHYSICAL PROPERTIES

Appearance	Colorless Clear Liquid
Odor	Slight Chemical
Specific Gravity	1.04
pH - 1% solution (normal)	9.0
Solubility	Complete
Foaming	Moderate to high depending on application method

EUROPEAN ORDERING INFORMATION

Order Number	Description	Container Size	Qty. per case
PC-4-55G-01-E	Process2Clean 4 Non-Sterile	208.197 Liters	1
PC-4-55G-02-E	Process2Clean 4 Sterile	208.197 Liters	1
PC-4-5G-01-E	Process2Clean 4 Non-Sterile	18.927 Liters	1
PC-4-5G-02-E	Process2Clean 4 Sterile	18.927 Liters	1
PC-4-1G-01-E	Process2Clean 4 Non-Sterile	3.785412 Liters	4
PC-4-1G-02-E	Process2Clean 4 Sterile	3.785412 Liters	4

ADDITIONAL DOCUMENTATION PACKAGES (Available Upon Request)

- Sample Lot Specific Certification
- Technical Product PDF File
- Material Safety Data Sheet
- Product Cleaning Validation Report
- Product Sterility Validation Report
- CORE Product Analysis

PROCESS 2 CLEAN

FOR CRITICAL CLEAN IN PLACE APPLICATIONS

five

NEUTRAL PH CLEANING ADDITIVE

610-644-8335

NEUTRAL PH CLEANING ADDITIVE

Available in Sterile and Non-Sterile Formulations

DESIGNED SPECIFICALLY FOR CRITICAL CLEAN IN PLACE APPLICATIONS

For use on:

Processing Equipment
Process Tanks and Vessels
Bioreactors
Derouging and Passivation Processes
High Pressure Spray Applications
Blending Equipment
Tablet Presses
Laboratory and Production Glassware Washing
Production and Testing Component Parts
Ultrasonic Cleaning
Animal Cages
Stainless Steel

For use in the following facilities:

Pharmaceutical
Biotechnology
Research and Development
Cosmetics
Medical Device
Food & Beverage
Animal

What is Important?

The appropriate use of clean in place cleaners warrants two concerns. The first concern relates to the ability of the specific detergent to remove existent product residues that may exist in either open or closed processes manufacturing equipment and vessels. The second concern is the ability to rinse free the product residue, any contamination that has entered and the clean in place detergent itself to assure that such surfaces are clean prior to the formulation and manufacturing of a new lot of product. In short, if one introduces contamination, may it be viable, non-viable or residual, then one must assure its removal. Thus **Process2Clean 5** is available in both a sterile (filtered at 0.2 microns and aseptically filtered) and non-sterile packaging configurations. The sterile versions are ultra clean and assure that less contamination is introduced to the system. Thus, sterilize in place (SIP) systems have less work to do.

Process2Clean 5 is a phosphate free, neutral pH detergent that improves the cleaning performance of all Veltek Associates, Inc. cleaners. This high performance concentrated liquid cleaning agent is specifically designed as a additive that works in conjunction with cleaning agents to reduce foaming and remove soils. The product is used with both high end low energy clean in place products in the pharmaceutical, biotechnology, cosmetic, medical device, food and beverage industries. The wide array of components provides a stabilized formula that is capable of cleaning a multitude of product and non-product contact surfaces. Together with our other formulations, **Process2Clean 5** is one of Veltek's most effective cleaning agents that is capable of removing a wide array of residues. This product was designed specifically for use in recirculation and high pressure cleaning applications. The product is extremely effective in removing residues that include a wide array of oils, waxes, grease and petrolatum.

PROCESS2CLEAN
FOR CRITICAL CLEAN IN PLACE APPLICATIONS

Process2Clean 5 is a low foaming cleaning agent (at all temperatures) and has enhanced cleaning and the ability to rinse free from systems. **Process2Clean 5** can be used in both CIP and COP applications. An extensive validation support package is available and is complimented with Veltek Associates, Inc.'s CORE (Critical Ongoing Residue Evaluation) Laboratory that can assist with specialized testing to meet your specific needs.

Feature	Benefit
An enhanced additive that decreases foaming and increases the efficiency of the surfactant in the detergent.	Increases the effectiveness against a wider array of soils. This product cleans with a multitude of chemistries safer than general solvents or commodity chemicals. It is extremely effective in removing residues that include a wide array of oils, waxes, grease and petrolatum.
Sterile and Non-Sterile Versions	At times, firms are concerned with not only the ability of the CIP product to clean and rinse free but also what has been introduced to the system by the CIP product. The sterile versions are filtered at 0.2 microns in a GMP Class 100 manufacturing area into presterilized containers. Each lot is tested for sterility via current USP compendium. The sterile version eliminates the concern for unwanted particulates, microorganisms and pyrogens that may be introduced through the CIP chemical.
Specific and non-specific methods to detect cleaning agent residues. The methods include HPLC, TOC, IC, IR, Freon and others	These methods can assist in the validation process of end users by eliminating the need for customers to develop their own analytical methods. The "CORE" System also develops specific methods unique to the customer's needs.
Complete Rinsing of Cleaning Agent Ingredients	The formula is designed to easily rinse free from product surfaces. Water rinse time period and volume is minimal. Meets the highest standard in manufacturing and processing.
All products are manufactured and tested from beginning to end in a FDA and EPA registered manufacturing facility.	Meets the highest standard in manufacturing and processing.
Lot Specific Documentation Package	All product is lot traceable and delivered each time with the lot specific certification. All lots are traced through the master batch records.
High Level of Quality	All products are made in controlled environments that include Class 100, Class 10,000 and Class 100,000. This assures the highest level of quality and cleanliness of the final product.
Phosphate Free Detergent	Environment Safe
Use concentrations range from 2% to 5%.	Dependent upon the requirements of the soil load to be cleaned varying concentrations are used to efficiently clean the existent residues in the shortest time period.

PHYSICAL PROPERTIES

Appearance	Colorless Clear Liquid
Odor	Slight Chemical
Specific Gravity	1.01
pH - 1% solution (normal)	8.55
Solubility	Complete
Foaming	Minimal due to product enhancements even at higher temperature applications

EUROPEAN ORDERING INFORMATION

Order Number	Description	Container Size	Qty. per case
PC-5-55G-01-E	Process2Clean 5 Non-Sterile	208.197 Liters	1
PC-5-55G-02-E	Process2Clean 5 Sterile	208.197 Liters	1
PC-5-5G-01-E	Process2Clean 5 Non-Sterile	18.927 Liters	1
PC-5-5G-02-E	Process2Clean 5 Sterile	18.927 Liters	1
PC-5-1G-01-E	Process2Clean 5 Non-Sterile	3.785412 Liters	4
PC-5-1G-02-E	Process2Clean 5 Sterile	3.785412 Liters	4

ADDITIONAL DOCUMENTATION PACKAGES (Available Upon Request)

- Sample Lot Specific Certification
- Technical Product PDF File
- Material Safety Data Sheet
- Product Cleaning Validation Report
- Product Sterility Validation Report
- CORE Product Analysis

PROCESS 2 CLEAN
FOR CRITICAL CLEAN IN PLACE APPLICATIONS

six

CHLORINATED ALKALINE CLEANING DETERGENT

610-644-8335

PROCESS2CLEAN
FOR CRITICAL CLEAN IN PLACE APPLICATIONS

CHLORINATED ALKALINE CLEANING DETERGENT

Available in Sterile and Non-Sterile Formulations

DESIGNED SPECIFICALLY FOR CRITICAL CLEAN IN PLACE APPLICATIONS

For use on:

Processing Equipment
Process Tanks and Vessels
Bioreactors
Blending Equipment
Tablet Presses
Production and Testing Component Parts
Laboratory Glassware
Ultrasonic Cleaning

For use in the following facilities:

Pharmaceutical
Biotechnology
Research and Development
Cosmetics
Medical Device
Food & Beverage

What is Important?

The appropriate use of clean in place cleaners warrants two concerns. The first concern relates to the ability of the specific detergent to remove existent product residues that may exist in either open or closed processes manufacturing equipment and vessels. The second concern is the ability to rinse free the product residue, any contamination that has entered and the clean in place detergent itself to assure that such surfaces are clean prior to the formulation and manufacturing of a new lot of product. In short, if one introduces contamination, may it be viable, non-viable or residual, then one must assure its removal. Thus **Process2Clean 6** is available in both a sterile (filtered at 0.2 microns and aseptically filtered) and non-sterile packaging configurations. The sterile versions are ultra clean and assure that less contamination is introduced to the system. Thus, sterilize in place (SIP) systems have less work to do.

Process2Clean 6 is a high performance concentrated liquid cleaning agent designed specifically for clean in place requirements in the pharmaceutical, biotechnology, cosmetic, medical device, food and beverage industries. **Process2Clean 6** is designed for use in low-energy agitated immersion systems, pressure spray applications, or manual washing application. It is extremely effective in cleaning ointments, creams, oils, waxes, greases and petrolatum-based products. **Process2Clean 6** can be used as a stand alone cleaner or as an additive to alkaline cleaners to enhance their cleaning capabilities. The wide array of components provides a stabilized formula that is capable of cleaning a multitude of product and non-product contact surfaces. The formulation is one of Veltek's most effective cleaning agents that is capable of specifically removing oils, waxes, creams and polymers.

PROCESS2CLEAN
FOR CRITICAL CLEAN IN PLACE APPLICATIONS

Process2Clean 6 is an enhanced cleaning with the ability to rinse free from systems. The phosphate free agent can be used in both CIP and COP applications. An extensive validation support package is available and is complimented with Veltek Associates, Inc.'s CORE (Critical Ongoing Residue Evaluation) Laboratory that can assist with specialized testing to meet your specific needs.

Feature	Benefit
Formulated chlorinated alkaline cleaner	Developed specifically for the removal of protein type soils. This product cleans with a multitude of chemistries safer than general solvents or commodity chemicals.
Sterile and Non-Sterile Versions	At times, firms are concerned with not only the ability of the CIP product to clean and rinse free but also what has been introduced to the system by the CIP product. The sterile versions are filtered at 0.2 microns in a GMP Class 100 manufacturing area into presterilized containers. Each lot is tested for sterility via current USP compendium. The sterile version eliminates the concern for unwanted particulates, microorganisms and pyrogens that may be introduced through the CIP chemical.
Specific and non-specific methods to detect cleaning agent residues. The methods include HPLC, TOC, IC, IR, Freon and others	These methods can assist in the validation process of end users by eliminating the need for customers to develop their own analytical methods. The "CORE" System also develops specific methods unique to the customer's needs.
Complete Rinsing of Cleaning Agent Ingredients	The formula is designed to easily rinse free from product surfaces. Water rinse time period and volume is minimal.
All products are manufactured and tested from beginning to end in a FDA and EPA registered manufacturing facility.	Meets the highest standard in manufacturing and processing.
Lot Specific Documentation Package	All product is lot traceable and delivered each time with the lot specific certification. All lots are traced through the master batch records.
High Level of Quality	All products are made in controlled environments that include Class 100, Class 10,000 and Class 100,000. This assures the highest level of quality and cleanliness of the final product.
Use concentrations range from 1% to 6%.	Dependent upon the requirements of the soil load to be cleaned varying concentrations are used to efficiently clean the existent residues in the shortest time period. The product is highly concentrated so less chemical agent needs to be used.

PHYSICAL PROPERTIES

Appearance	Amber Clear Liquid
Odor	Chlorine
Specific Gravity	1.15
pH - 1% solution (normal)	12.0
Solubility	Complete
Chlorine Content	Minimal - 1.0-2.0 percent
Foaming	Minimal due to product enhancements and even less at higher temperature applications
Rinsing	Excellent

EUROPEAN ORDERING INFORMATION

Order Number	Description	Container Size	Qty. per case
PC-6-55G-01-E	Process2Clean 6 Non-Sterile	208.197 Liters	1
PC-6-55G-02-E	Process2Clean 6 Sterile	208.197 Liters	1
PC-6-5G-01-E	Process2Clean 6 Non-Sterile	18.927 Liters	1
PC-6-5G-02-E	Process2Clean 6 Sterile	18.927 Liters	1
PC-6-1G-01-E	Process2Clean 6 Non-Sterile	3.785412 Liters	4
PC-6-1G-02-E	Process2Clean 6 Sterile	3.785412 Liters	4

ADDITIONAL DOCUMENTATION PACKAGES (Available Upon Request)

- Sample Lot Specific Certification
- Technical Product PDF File
- Material Safety Data Sheet
- Product Cleaning Validation Report
- Product Sterility Validation Report
- CORE Product Analysis

PRODUCT	DESCRIPTION
Cage2Wash1	Alkaline Detergent
Cage2Wash2	Enhanced Alkaline Detergent
Cage2Wash3	Acid Based Detergent
Cage2Wash4	Hydroxyacetic Acid Detergent
Cage2Wash5	Citric Acid Cleaner/Descaler Detergent

WELCOME TO CAGE2WASH

Cage2Wash products have been specifically designed for **critical animal facility, component and animal cage washing applications**. In this venue, the appropriate use of a cleaning agent to remove animal waste and animal by products is critical. The use of a cleaning agent in this venue warrants an end user to concern themselves with the ability of the specific detergent to remove the existent residues. These residues may be in the form of urine, scales, animal fats, oils, organics and other related animal by-products or formulated drug product residues. Such residues need to be effectively removed through a variety of application methodologies that include rinsing, high pressure spray, circulation and immersion. The removal of past product residues and/or animal by-products protects the integrity of new product lots and animals that may be placed into the cages. Cage2Wash products also have the ability to rinse free from the surfaces thus eliminating the possibility of the residual from the cleaner itself corrupting the system. These concerns are critical considerations for lab animal research and lab animal housing facilities.

Cage2Wash products have been engineered to effectively remove a multitude of product residues. All products are formulated under the highest quality standards in a GMP manufacturing facility.

CAGE2WASH

one

ALKALINE DETERGENT

610-644-8335

CAGE2WASH

ALKALINE DETERGENT

Specifically Designed for Animal Research and Manufacturing Facilities

DESIGNED SPECIFICALLY FOR CRITICAL CLEAN IN PLACE APPLICATIONS

For use on:

Stainless Steel
Processing Equipment
Laboratory Glassware
Plastics
Polycarbonates
Equipment
Aluminum
Animal Cages
Medical Devices Applications

For use in the following facilities:

Pharmaceutical
Biotechnology
Animal
Research and Development
Cosmetics
Medical Device
Food & Beverage

What is Important?

The appropriate use of clean in place cleaners warrants two concerns. The first concern relates to the ability of the specific detergent to remove existent product residues that may exist in either open or closed processes manufacturing equipment, animal cages and vessels. The second concern is the ability to rinse free the product residue, any contamination that has entered and the clean in place detergent itself to assure that such surfaces are clean prior to the formulation and manufacturing of a new lot of product or the replacement of an animal.

Cage2Wash 1 is a high performance concentrated liquid alkaline cleaning agent designed specifically for clean in place requirements in the pharmaceutical, biotechnology, cosmetic, medical device, food and beverage industries. **Cage2Wash 1** is formulated with potassium hydroxide, surfactants, chelating agents, and other critically essential cleaning ingredients. The wide array of components provides a stabilized formula that is capable of cleaning a multitude of product and non-product contact surfaces. The formulation is Veltek's most effective broad spectrum cleaning agent that is capable of removing a wide array of residues. This product is extremely effective in removing residues that include a wide array of proteins, excipients, fine chemicals, silicones, oils, petrolatum, polymers, serums, proteins, urine, scales, animal fats, oils and most all types of organics. **Cage2Wash 1** is safe for use on stainless steel, aluminum, copper, galvanized steel, soft metals, glass, polypropylene, polycarbonates and a wide variety of plastics.

CAGE2WASH

Cage2Wash 1 is a low foaming cleaning agent (at all temperatures) and has enhanced cleaning ability to rinse free from systems. The phosphate free agent can be used in both CIP and COP applications. An extensive validation support package is available and is complimented with Veltek Associates, Inc.'s CORE (Critical Ongoing Residue Evaluation) Laboratory that can assist with specialized testing to meet your specific needs.

Feature	Benefit
A low foaming, phosphate free formulated alkaline cleaner	This product cleans with a multitude of chemistries safer than general solvents or commodity chemicals. It is extremely effective in removing residues that include a wide array of proteins, excipients, fine chemicals, silicones, oils, petrolatum, polymers, serums, proteins, urine, scales, animal fats, oils and most all types of organics.
Specific and non-specific methods to detect cleaning agent residues. The methods include HPLC, TOC, IC, IR, Freon and others	These methods can assist in the validation process of end users by eliminating the need for customers to develop their own analytical methods. The "CORE" System also develops specific methods unique to the customer's needs.
Complete Rinsing of Cleaning Agent Ingredients	The formula is designed to easily rinse free from product surfaces. Water rinse time period and volume is minimal.
All products are manufactured and tested from beginning to end in a FDA and EPA registered manufacturing facility.	Meets the highest standard in manufacturing and processing.
Lot Specific Documentation Package	All product is lot traceable and delivered each time with the lot specific certification. All lots are traced through the master batch records.
High Level of Quality	All products are made in controlled environments that include Class 100, Class 10,000 and Class 100,000. This assures the highest level of quality and cleanliness of the final product.
Phosphate Free Detergent	Environment Safe
Use concentrations range from .2% to 5%.	Dependent upon the requirements of the soil load to be cleaned varying concentrations are used to efficiently clean the existent residues in the shortest time period.

PHYSICAL PROPERTIES	
Appearance	Colorless Clear Liquid
Odor	Slight Chemical
Specific Gravity	1.25
pH - 1% solution (normal)	12.5
Solubility	Complete
Chlorine Content	Minimal - 1.0-2.0 percent
Foaming	Minimal due to product enhancements
Rinsing	Excellent

EUROPEAN ORDERING INFORMATION

Order Number	Description	Container Size	Qty. per case
C-1-55G-01-E	Cage2Wash 1 Non-Sterile	208.197 Liters	1
C-1-5G-01-E	Cage2Wash 1 Non-Sterile	18.927 Liters	1
C-1-1G-01-E	Cage2Wash 1 Non-Sterile	3.785412 Liters	4

ADDITIONAL DOCUMENTATION PACKAGES (Available Upon Request)

- Sample Lot Specific Certification
- Technical Product PDF File
- Material Safety Data Sheet
- Product Cleaning Validation Report
- CORE Product Analysis

CAGE2WASH

two

ENHANCED ALKALINE DETERGENT

610-644-8335

CAGE2WASH

ENHANCED ALKALINE DETERGENT

Specifically Designed for Animal Research and Manufacturing Facilities

DESIGNED SPECIFICALLY FOR CRITICAL CLEAN IN PLACE APPLICATIONS

For use on:

Stainless Steel
Processing Equipment
Laboratory Glassware
Plastics
Polycarbonates
Equipment
Aluminum
Low Grade Metals
Animal Cages
Medical Devices Applications

For use in the following facilities:

Pharmaceutical
Biotechnology
Animal
Research and Development
Cosmetics
Medical Device
Food & Beverage

What is Important?

The appropriate use of clean in place cleaners warrants two concerns. The first concern relates to the ability of the specific detergent to remove existent product residues that may exist in either open or closed processes manufacturing equipment, animal cages and vessels. The second concern is the ability to rinse free the product residue, any contamination that has entered and the clean in place detergent itself to assure that such surfaces are clean prior to the formulation and manufacturing of a new lot of product or the replacement of an animal.

Cage2Wash 2 is an enhanced high performance concentrated liquid alkaline cleaning agent designed specifically for clean in place requirements in the pharmaceutical, biotechnology, animal, cosmetic, medical device, food and beverage industries. **Cage2Wash 2** is formulated with high surfactant levels, chelating agents, and other critically essential cleaning ingredients. The wide array of components provides a stabilized formula that is capable of cleaning a multitude of product and non-product contact surfaces. The formulation is effective in removing a wide array of residues. This product is extremely effective in removing residues that include a wide array of proteins, excipients, fine chemicals, silicones, oils, petrolatum, polymers, serums, proteins, urine, scales, animal fats, oils and most all types of organics. **Cage2Wash 2** is safe for use on stainless steel, aluminum, copper, galvanized steel, soft metals, glass, polypropylene, polycarbonates and a wide variety of plastics.

CAGE2WASH

Cage2Wash 2 is a low foaming cleaning agent (at all temperatures) and has enhanced cleaning ability to rinse free from systems. The phosphate free agent can be used in both CIP and COP applications. An extensive validation support package is available and is complimented with Veltek Associates, Inc.'s CORE (Critical Ongoing Residue Evaluation) Laboratory that can assist with specialized testing to meet your specific needs.

Feature	Benefit
A low foaming, enhanced, phosphate free formulated alkaline cleaner	This product cleans with a multitude of chemistries safer than general solvents or commodity chemicals. It is extremely effective in removing residues that include a wide array of proteins, excipients, fine chemicals, silicones, oils, petrolatum, polymers, serums, proteins, urine, scales, animal fats, oils and most all types of organics.
Specific and non-specific methods to detect cleaning agent residues. The methods include HPLC, TOC, IC, IR, Freon and others	These methods can assist in the validation process of end users by eliminating the need for customers to develop their own analytical methods. The "CORE" System also develops specific methods unique to the customer's needs.
Complete Rinsing of Cleaning Agent Ingredients	The formula is designed to easily rinse free from product surfaces. Water rinse time period and volume is minimal.
All products are manufactured and tested from beginning to end in a FDA and EPA registered manufacturing facility.	Meets the highest standard in manufacturing and processing.
Lot Specific Documentation Package	All product is lot traceable and delivered each time with the lot specific certification. All lots are traced through the master batch records.
High Level of Quality	All products are made in controlled environments that include Class 100, Class 10,000 and Class 100,000. This assures the highest level of quality and cleanliness of the final product.
Phosphate Free Detergent	Environment Safe
Use concentrations range from .2% to 5%.	Dependent upon the requirements of the soil load to be cleaned varying concentrations are used to efficiently clean the existent residues in the shortest time period.

PHYSICAL PROPERTIES

Appearance	Amber Clear Liquid
Odor	Slight Chemical
Specific Gravity	1.28
pH - 1% solution (normal)	13.0
Solubility	Complete
Foaming	Minimal due to product enhancements
Rinsing	Excellent

EUROPEAN ORDERING INFORMATION

Order Number	Description	Container Size	Qty. per case
C-2-55G-01-E	Cage2Wash 2 Non-Sterile	208.197 Liters	1
C-2-5G-01-E	Cage2Wash 2 Non-Sterile	18.927 Liters	1
C-2-1G-01-E	Cage2Wash 2 Non-Sterile	3.785412 Liters	4

ADDITIONAL DOCUMENTATION PACKAGES (Available Upon Request)

- Sample Lot Specific Certification
- Technical Product PDF File
- Material Safety Data Sheet
- Product Cleaning Validation Report
- CORE Product Analysis

CAGE 2 WASH

three

ACIDIC BASED DETERGENT

610-644-8335

CAGE2WASH

ACID BASED DETERGENT

Specifically Designed for Animal Research and Manufacturing Facilities

DESIGNED SPECIFICALLY FOR CRITICAL CLEAN IN PLACE APPLICATIONS

For use on:

Stainless Steel
Processing Equipment
Laboratory Glassware
Plastics
Polycarbonates
Equipment
Aluminum
Animal Cages
Carbon & Urine Scales
Medical Devices Applications

For use in the following facilities:

Pharmaceutical
Biotechnology
Research and Development
Cosmetics
Medical Device
Food & Beverage
Animal

What is Important?

The appropriate use of clean in place cleaners warrants two concerns. The first concern relates to the ability of the specific detergent to remove existent product residues that may exist in either open or closed processes manufacturing equipment, animal cages and vessels. The second concern is the ability to rinse free the product residue, any contamination that has entered and the clean in place detergent itself to assure that such surfaces are clean prior to the formulation and manufacturing of a new lot of product or the replacement of an animal.

Cage2Wash 3 is a high performance concentrated phosphoric/citric acid liquid cleaning agent designed specifically for clean in place requirements in the pharmaceutical, biotechnology, cosmetic, medical device, animal, food and beverage industries. **Cage2Wash 3** is formulated with phosphoric acid, surfactants, chelating agents, and other critically essential cleaning ingredients. The wide array of components provides a stabilized formula that is capable of cleaning a multitude of product and non-product contact surfaces. The formulation is Veltek's most effective acid cleaning agent that is capable of removing a wide array of residues. This product is extremely effective in removing residues that include a wide array of inorganic salts, scales, particulate carbon, urine scales (on polycarbonate, stainless and other caging materials), proteins, excipients, fine chemicals, silicones, oils, petrolatum, polymers and most all types of organics. Routine use of this product reduces corrosion, pitting and rusting.

Cage2Wash 3 is a low foaming cleaning agent (at all temperatures) and has enhanced cleaning ability to rinse free from systems. The phosphate free agent can be used in both CIP and COP applications. An extensive validation support package is available and is complimented with Veltek Associates, Inc.'s CORE (Critical Ongoing Residue Evaluation) Laboratory that can assist with specialized testing to meet your specific needs.

Feature	Benefit
A low foaming, phosphate free formulated acid cleaner	This product cleans with a multitude of chemistries safer than general solvents or commodity chemicals. It is extremely effective in removing residues that include a wide array of inorganic salts, scales, particulate carbon, urine scales (on polycarbonate, stainless and other caging materials), proteins, excipients, fine chemicals, silicones, oils, petrolatum, polymers and most all types of organics.
Specific and non-specific methods to detect cleaning agent residues. The methods include HPLC, TOC, IC, IR, Freon and others	These methods can assist in the validation process of end users by eliminating the need for customers to develop their own analytical methods. The "CORE" System also develops specific methods unique to the customer's needs.
Complete Rinsing of Cleaning Agent Ingredients	The formula is designed to easily rinse free from product surfaces. Water rinse time period and volume is minimal.
All products are manufactured and tested from beginning to end in a FDA and EPA registered manufacturing facility.	Meets the highest standard in manufacturing and processing.
Lot Specific Documentation Package	All product is lot traceable and delivered each time with the lot specific certification. All lots are traced through the master batch records.
High Level of Quality	All products are made in controlled environments that include Class 100, Class 10,000 and Class 100,000. This assures the highest level of quality and cleanliness of the final product.
Phosphate Free Detergent	Environment Safe
Use concentrations range from .15% to 5%.	Dependent upon the requirements of the soil load to be cleaned varying concentrations are used to efficiently clean the existent residues in the shortest time period.

PHYSICAL PROPERTIES	
Appearance	Colorless Clear Liquid
Odor	Slight Chemical
Specific Gravity	1.35
pH - 1% solution (normal)	2.0
Solubility	Complete
Foaming	Minimal due to product enhancements
Rinsing	Excellent

EUROPEAN ORDERING INFORMATION

Order Number	Description	Container Size	Qty. per case
C-3-55G-01-E	Cage2Wash 3 Non-Sterile	208.197 Liters	1
C-3-5G-01-E	Cage2Wash 3 Non-Sterile	18.927 Liters	1
C-3-1G-01-E	Cage2Wash 3 Non-Sterile	3.785412 Liters	4

ADDITIONAL DOCUMENTATION PACKAGES (Available Upon Request)

- Sample Lot Specific Certification
- Technical Product PDF File
- Material Safety Data Sheet
- Product Cleaning Validation Report
- CORE Product Analysis

CAGE2WASH

four

HYDROXYACETIC ACID DETERGENT

610-644-8335

CAGE2WASH

HYDROXYACETIC ACID DETERGENT

Specifically Designed for Animal Research and Manufacturing Facilities

DESIGNED SPECIFICALLY FOR CRITICAL CLEAN IN PLACE APPLICATIONS

For use on:

Processing Equipment
Process Tanks and Vessels
Bioreactors
Derouging and Passivation Processes
High Pressure Spray Applications
Blending Equipment
Tablet Presses
Laboratory and Production Glassware Washing
Production and Testing Component Parts
Ultrasonic Cleaning
Animal Cages
Carbon & Urine Scales
Stainless Steel
Plastics
Polycarbonates
Aluminum
Medical Devices Applications

For use in the following facilities:

Pharmaceutical
Biotechnology
Research and Development
Cosmetics
Medical Device
Food & Beverage
Animal

What is Important?

The appropriate use of clean in place cleaners warrants two concerns. The first concern relates to the ability of the specific detergent to remove existent product residues that may exist in either open or closed processes manufacturing equipment, animal cages and vessels. The second concern is the ability to rinse free the product residue, any contamination that has entered and the clean in place detergent itself to assure that such surfaces are clean prior to the formulation and manufacturing of a new lot of product or the replacement of an animal.

Cage2Wash 4 is a high performance concentrated hydroxyacetic acid cleaner/descaler liquid cleaning agent designed specifically for clean in place requirements in the pharmaceutical, biotechnology, cosmetic, medical device, food and beverage industries. **Cage2Wash 4** is formulated with phosphoric acid, surfactants, chelating agents, and other critically essential cleaning ingredients. The wide array of components provides a stabilized formula that is capable of cleaning a multitude of product and non-product contact surfaces. The formulation is one of Veltek's most effective acid cleaning agents that is capable of removing a wide array of residues. This product was designed specifically for use in high pressure cleaning applications. The product is extremely effective in removing residues that include a wide array of inorganic salts, scales, particulate carbon, urine scales (on polycarbonate, stainless and other caging materials), proteins, excipients, fine chemicals, silicones, oils, petrolatum, polymers and most all types of organics. Routine use of this product is helpful in removal of free metals and reduces corrosion, pitting and rusting.

Cage2Wash 4 is a low foaming cleaning agent (at all temperatures) and has enhanced cleaning ability to rinse free from systems. The phosphate free agent can be used in both CIP and COP applications. An extensive validation support package is available and is complimented with Veltek Associates, Inc.'s CORE (Critical Ongoing Residue Evaluation) Laboratory that can assist with specialized testing to meet your specific needs.

Feature	Benefit
A low foaming, phosphate free formulated acid cleaner	This product cleans with a multitude of chemistries safer than general solvents or commodity chemicals. It is extremely effective in removing residues that include a wide array of inorganic salts, scales, particulate carbon, urine scales (on polycarbonate, stainless and other caging materials), proteins, excipients, fine chemicals, silicones, oils, petrolatum, polymers and most all types of organics.
Specific and non-specific methods to detect cleaning agent residues. The methods include HPLC, TOC, IC, IR, Freon and others	These methods can assist in the validation process of end users by eliminating the need for customers to develop their own analytical methods. The "CORE" System also develops specific methods unique to the customer's needs.
Complete Rinsing of Cleaning Agent Ingredients	The formula is designed to easily rinse free from product surfaces. Water rinse time period and volume is minimal.
All products are manufactured and tested from beginning to end in a FDA and EPA registered manufacturing facility.	Meets the highest standard in manufacturing and processing.
Lot Specific Documentation Package	All product is lot traceable and delivered each time with the lot specific certification. All lots are traced through the master batch records.
High Level of Quality	All products are made in controlled environments that include Class 100, Class 10,000 and Class 100,000. This assures the highest level of quality and cleanliness of the final product.
Phosphate Free Detergent	Environment Safe
Use concentrations range from 0.15% to 5%.	Dependent upon the requirements of the soil load to be cleaned varying concentrations are used to efficiently clean the existent residues in the shortest time period.

PHYSICAL PROPERTIES

Appearance	Colorless Clear Liquid
Odor	Slight Chemical
Specific Gravity	1.12
pH - 1% solution (normal)	2.8
Solubility	Complete
Foaming	Minimal due to product enhancements
Rinsing	Excellent

EUROPEAN ORDERING INFORMATION

Order Number	Description	Container Size	Qty. per case
C-4-55G-01-E	Cage2Wash 4 Non-Sterile	208.197 Liters	1
C-4-5G-01-E	Cage2Wash 4 Non-Sterile	18.927 Liters	1
C-4-1G-01-E	Cage2Wash 4 Non-Sterile	3.785412 Liters	4

ADDITIONAL DOCUMENTATION PACKAGES (Available Upon Request)

- Sample Lot Specific Certification
- Technical Product PDF File
- Material Safety Data Sheet
- Product Cleaning Validation Report
- CORE Product Analysis

CAGE2WASH

five

CITRIC ACID
CLEANER/DESCALER
DETERGENT

610-644-8335

CAGE2WASH

CITRIC ACID CLEANER/DESCALER DETERGENT

Specifically Designed for Animal Research and Manufacturing Facilities

DESIGNED SPECIFICALLY FOR CRITICAL CLEAN IN PLACE APPLICATIONS

For use on:

Stainless Steel
Processing Equipment
Laboratory Glassware
Plastics
Polycarbonates
Equipment
Aluminum
Animal Cages
Carbon & Urine Scales
Medical Devices Applications

For use in the following facilities:

Pharmaceutical
Biotechnology
Animal
Research and Development
Cosmetics
Medical Device
Food & Beverage

What is Important?

The appropriate use of clean in place cleaners warrants two concerns. The first concern relates to the ability of the specific detergent to remove existent product residues that may exist in either open or closed processes manufacturing equipment, animal cages and vessels. The second concern is the ability to rinse free the product residue, any contamination that has entered and the clean in place detergent itself to assure that such surfaces are clean prior to the formulation and manufacturing of a new lot of product or the replacement of an animal.

Cage2Wash 5 is a high performance concentrated liquid organic acid cleaner/descaler cleaning agent designed specifically for clean in place requirements in the pharmaceutical, biotechnology, animal, cosmetic, medical device, food and beverage industries. **Cage2Wash 5** is formulated with citric acid, surfactants, chelating agents, and other critically essential cleaning ingredients. The wide array of components provides a stabilized formula that is capable of cleaning a multitude of product and non-product contact surfaces. This product is extremely effective in removing residues that include a wide array of inorganic salts, scales, particulate carbon, urine, animal fats, oils and most all types of organics. **Cage2Wash 5** is safe for use on stainless steel, aluminum, galvanized steel, soft metals, glass, polypropylene, polycarbonates and a wide variety of plastics. The product is an excellent choice for racking and cage wash machines.

CAGE2WASH

Cage2Wash 5 is a low foaming cleaning agent (at all temperatures) and has enhanced cleaning ability to rinse free from systems. The phosphate free agent can be used in both CIP and COP applications. An extensive validation support package is available and is complimented with Veltek Associates, Inc.'s CORE (Critical Ongoing Residue Evaluation) Laboratory that can assist with specialized testing to meet your specific needs.

Feature	Benefit
A low foaming, phosphate free formulated citric acid cleaner	This product cleans with a multitude of chemistries safer than general solvents or commodity chemicals. It is extremely effective in removing residues that include a wide array of inorganic salts, scales, particulate carbon, urine, animal fats, oils and most all types of organics.
Specific and non-specific methods to detect cleaning agent residues. The methods include HPLC, TOC, IC, IR, Freon and others	These methods can assist in the validation process of end users by eliminating the need for customers to develop their own analytical methods. The "CORE" System also develops specific methods unique to the customer's needs.
Complete Rinsing of Cleaning Agent Ingredients	The formula is designed to easily rinse free from product surfaces. Water rinse time period and volume is minimal.
All products are manufactured and tested from beginning to end in a FDA and EPA registered manufacturing facility.	Meets the highest standard in manufacturing and processing.
Lot Specific Documentation Package	All product is lot traceable and delivered each time with the lot specific certification. All lots are traced through the master batch records.
High Level of Quality	All products are made in controlled environments that include Class 100, Class 10,000 and Class 100,000. This assures the highest level of quality and cleanliness of the final product.
Phosphate Free Detergent	Environment Safe
Use concentrations range from 0.2% to 5%.	Dependent upon the requirements of the soil load to be cleaned varying concentrations are used to efficiently clean the existent residues in the shortest time period.

PHYSICAL PROPERTIES

Appearance	Amber Clear Liquid
Odor	Slight Chemical
Specific Gravity	1.25
pH - 1% solution (normal)	1.0
Solubility	Complete
Foaming	Minimal due to product enhancements
Rinsing	Excellent

EUROPEAN ORDERING INFORMATION

Order Number	Description	Container Size	Qty. per case
C-5-55G-01-E	Cage2Wash 5 Non-Sterile	208.197 Liters	1
C-5-5G-01-E	Cage2Wash 5 Non-Sterile	18.927 Liters	1
C-5-1G-01-E	Cage2Wash 5 Non-Sterile	3.785412 Liters	4

ADDITIONAL DOCUMENTATION PACKAGES (Available Upon Request)

- Sample Lot Specific Certification
- Technical Product PDF File
- Material Safety Data Sheet
- Product Cleaning Validation Report
- CORE Product Analysis

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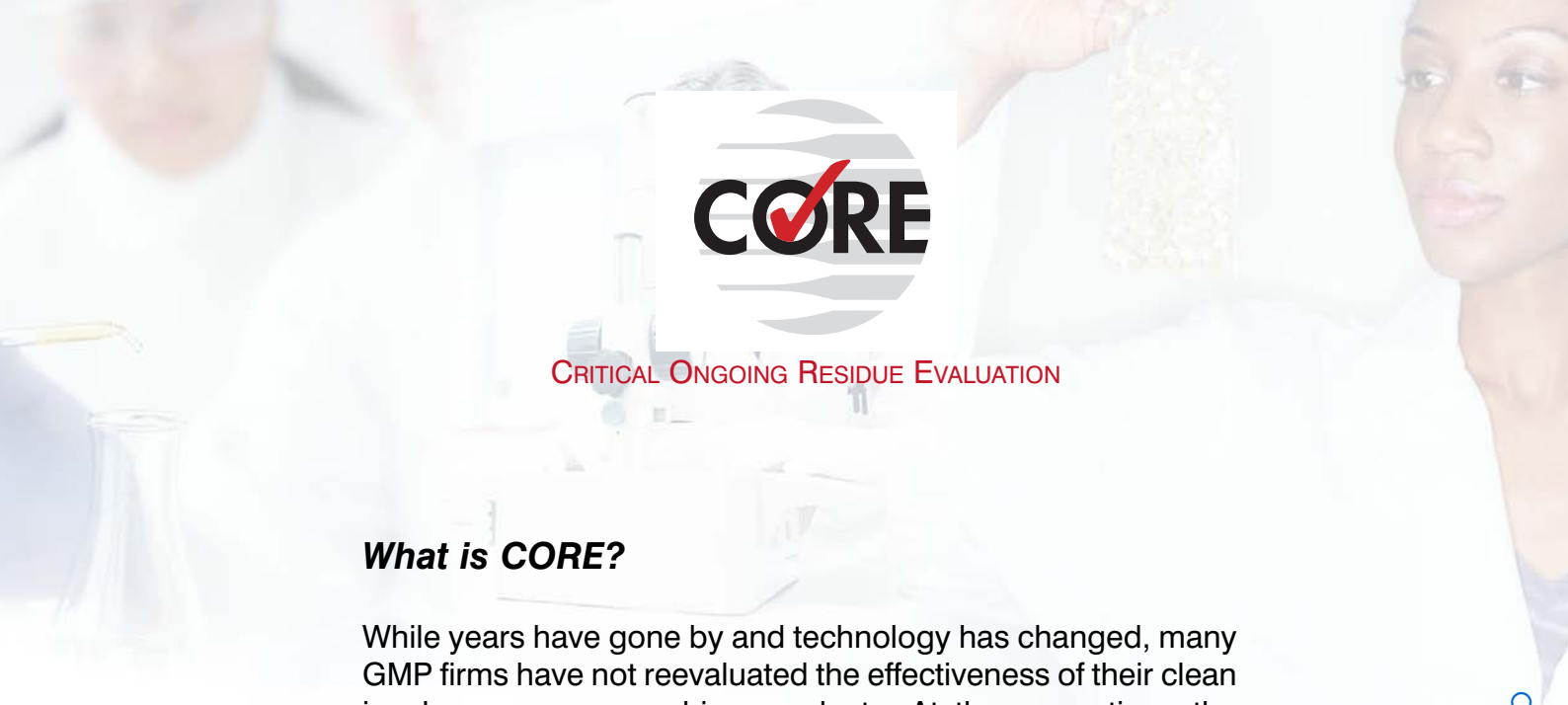


CRITICAL ONGOING RESIDUE EVALUATION

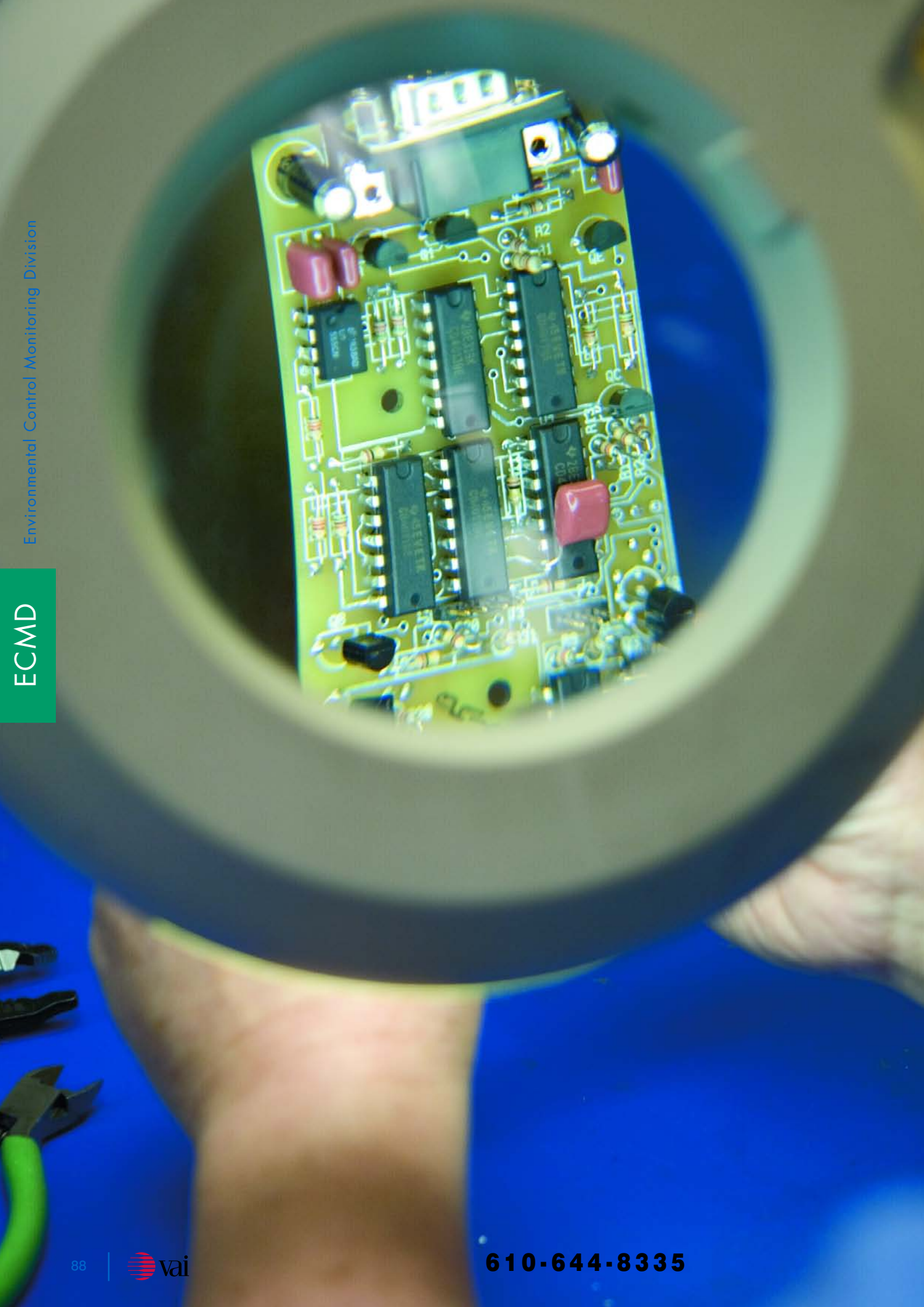
What is CORE?

While years have gone by and technology has changed, many GMP firms have not reevaluated the effectiveness of their clean in place or cage washing products. At the same time, the industry grows and new operations manufacturing new products blossom each day. In both scenarios, the need for routine evaluations to be conducted is essential. In the competitive world, cleaning down time costs firms enormous amounts of overhead time and money. Normally these costs can be dramatically reduced by the use of more efficient and state of the art detergents that work specifically against residues in current times. At the same time, firms also find that combination cleanings, not in present scopes reduce the amount of cleaning time, cleaning chemicals used and the level of personnel required to clean critical surfaces.

The CORE (Critical Ongoing Residue Evaluation) System is a service offered within the VAI Laboratories division of Veltek Associates, Inc. The focus of the division is to provide our clients with a specialized laboratory service that can assist them in performing product contact cleaning validation studies as an external service. This department utilized user surfaces and user product residues in our unique CORE Analysis Chamber to determine the level of cleaning achieved by detergents that are utilized in operations.

The CORE System provides an excellent means to define where present systems are and where they want to be in the future. May it be an older operation or a new operation, the CORE System provides the requirements necessary to meet both internal requirements and external regulatory expectations. Please contact your Veltek Associates, Inc. Technical Sales Representative or Veltek Associates, Inc. directly about this invaluable service.

ECMD



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WELCOME TO ECMD

ENVIRONMENTAL CONTROL MONITORING DIVISION

ECMD or VAI's Environmental Control Monitoring Division has addressed the needs of the Pharmaceutical, Biotechnology, Semi-Conductor, and Electronics industries by designing a complete range of air testing equipment that addresses viable air sampling and the contamination levels of products deemed suitable for clean room operations.

VAI's ECMD manufactures the SMA™ Microbial Air Sampler Systems, the Helmke-Yeich™ (H-Y) Tumble Drum Tester and the VTC™ Variable Temperature Controller.

The SMA Microbial Air Sampler Systems are designed to test air within the clean room setting for discerning the level of viable contamination that is present in a volume of air. As one of the premier sampling methods in the pharmaceutical and biotechnology industries for over 11 years, the SMA Micro Sampler Systems offer a complete range of products to meet all requirements for quantitative microbial air testing. The SMA Systems include the SMA Atrium, SMA Remote Sampler, SMA Compressed Air Sampler, SMA CC Control Centers, SMA ISO-CC Control Centers and the SMA MicroPortable.

The SMA Atrium and Control Centers with OneTouch Command Systems features provide the ability to test multi-locations and incorporate a facility wide monitoring system. Outlined in the pages to follow, the SMA Micro Sampler Systems and SMA One Touch Command Systems are available in models that test from one (1) to ten (10) locations. The SMA ISO-CC Control Centers are designed for use with isolators or barrier systems and incorporate OneTouch Command System features for testing 1 to 10 locations simultaneously or independently.

In addition to our facility monitoring systems, the SMA MicroPortable is a battery operated unit that provides portability for the testing of viable airborne contaminates. The SMA Compressed Air Sampler with portable and stationary devices to assist in delineating the microbial levels of compressed air and gas systems.

ECMD also manufactures the H-Y Tumble Drum Tester. The H-Y Tumble Drum Tester is a recommended method for testing and disseminating the inherent contamination levels of products deemed suitable for the controlled environment by the Institute of Environmental Sciences RP3.

ECMD's VTC Controller provides for the evaluation of particulates within a volume of air from high temperature applications up to 1250ºF. These products are described on the following pages.

ECMD-ENVIRONMENTAL CONTROL MONITORING DIVISION

91	SMA Atrium
92	SMA Remote Atrium
93	SMA Compressed Air Sampler
94-95	SMA Control Centers
96	SMA Wireless Control Panels
97-99	SMA OneTouch
100	SMA ISO-CC Isolator
101	SMA MicroPortable
102	How to purchase an SMA system
109	HY Tumble Drum Tester
110	VTC

SMA™ ATRIUM

For over 22 years, the SMA Atrium has been the chosen test method of many pharmaceutical and biotechnology organizations for determining the level of existent microbial contaminants in their manufacturing operations.

FEATURES:

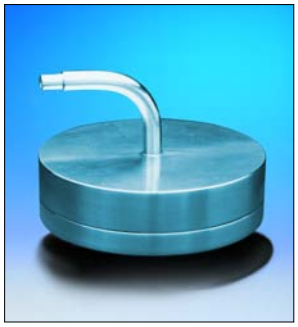
- Can be completely sterilized by steam, heat or ETO
- Constructed of either anodized aluminum, or 316L Stainless Steel
- Durable and low maintenance
- 4-1/2" in diameter by 1-1/2" in height
- Compact size allows the sampling device to be located near filling processes where space is limited
- Reports accurately the air quality near fill areas and reduce false positives from operators
- Operates at an air flow of 1 cubic foot per minute (1CFM)
- Designed to provide a tortuous path that air must travel, which assures a 95% capture efficiency of 0.5 micron particles and larger
- 12 top orifices available in 1/2", 1/4" and 3/32" provide the ability to sample for varying time periods
  - Top orifice size is dependent upon the desired exposure time versus desiccation of the nutrient media
  - 3/32" top orifice allows a maximum 60 minute exposure time
  - 1/2" and 1/4" top orifices allow up to 4 hours of exposure time (dependent upon conditions)
- Utilizes a 100 mm plate filled to either 25mL or 32mL of nutrient media (common fill levels from most suppliers)
  - The 25mL fill provides the ability to sample up to 90 minutes on one agar plate
  - The 32mL fill provides the ability to sample up to 4 hours on one agar plate (dependent upon conditions)
- Requires only a vacuum source to operate
  - Sources can be either central vacuum systems or one of the VAI 1 thru 10 location control centers

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

SMA Atrium Validation Report
SMA Atrium User Manual

Order#	Atrium Description
SMA-316-T-18-1/4	316 Stainless Steel SMA 18 ml. fill Top Only
SMA-316-T-18-1/2	316 Stainless Steel SMA 18 ml. fill Top Only
SMA-316-T-25-1/4	316 Stainless Steel SMA 25 ml. fill Top Only
SMA-316-T-25-1/2	316 Stainless Steel SMA 25 ml. fill Top Only
SMA-316-T-32-1/4	316 Stainless Steel SMA 32 ml. fill Top Only
SMA-316-T-32-1/2	316 Stainless Steel SMA 32 ml. fill Top Only
SMA-316-18-OB	316 Stainless Steel SMA 18 ml. fill Bottom Only
SMA-316-25-OB	316 Stainless Steel SMA 25 ml. fill Bottom Only
SMA-316-32-OB	316 Stainless Steel SMA 32 ml. fill Bottom Only

SMA™ REMOTE ATRIUM



In some instances the use of the SMA Remote Atrium may be necessary when the size of the SMA Atrium, while small, may be too large to fit into a location deemed critical to be tested for microbial contaminants.

FEATURES:

- Designed with one extension tube protruding from the top that serves as a connection point for either disposable tubing or stainless steel connections
- Able to be located away from the point of sample
- Can be completely sterilized via steam, heat or ETO
- Constructed of 316L Stainless Steel
- Durable and low maintenance
- 4-1/2" in diameter by 1-1/2" in height
- Compact size allows the sampling device to be located near filling processes where space is limited
- Reports accurately the air quality near fill areas and reduce false positives from operators
- Operates at an air flow of 1 cubic foot per minute (1CFM)
- Designed to provide a tortuous path that air must travel, which assures a 95% capture efficiency of 0.5 micron particles and larger
- Integrates a 3/8" ID connection that easily attaches to pre-sterilized tubing
- Utilizes a 100 mm plate filled to either 25mL or 32mL of nutrient media (common fill levels from most suppliers)
  - The 25mL fill provides the ability to sample up to 60 minutes on one agar plate
  - The 32mL fill provides the ability to sample up to 2 hours on one agar plate (dependent upon conditions)
- Requires only a vacuum source to operate
  - Sources can be either central vacuum systems or one of the VAI 1 thru 10 location control centers

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

SMA Atrium Validation Report
SMA Atrium User Manual

Order#	Atrium Description
SMA-316-RE-18	Complete Atrium 316 Stainless Steel REMOTE SMA 18 ml. fill
SMA-316-RE-18-OB	316 Stainless Steel REMOTE SMA 18 ml. fill Bottom Only
SMA-316-RE-TO-18	316 Stainless Steel REMOTE SMA 18 ml. fill Top Only
SMA-316-RE-25	Complete Atrium 316 Stainless Steel REMOTE SMA Complete Unit 25 ml. fill
SMA-316-RE-25-OB	316 Stainless Steel REMOTE SMA 25 ml. fill Bottom Only
SMA-316-RE-TO-25	316 Stainless Steel REMOTE SMA 25 ml. fill Top Only
SMA-316-RE-32	Complete Atrium 316 Stainless Steel REMOTE SMA Complete Unit 32 ml. fill
SMA-316-RE-32-OB	316 Stainless Steel REMOTE SMA 32 ml. fill Bottom Only
SMA-316-RE-TO-32	316 Stainless Steel REMOTE SMA 32 ml. fill Top Only

SMA™ COMPRESSED AIR SAMPLER

The SMA Compressed Air/Gas Atrium is used for the quantitative collection of microorganisms that may be present in compressed air and gas lines. The design and construction assures that a sterile test instrument is present to evaluate possible viable contaminants.

FEATURES:

- Can be completely sterilized by steam, heat or ETO
- Constructed of either anodized aluminum, 316L Stainless Steel
- Durable and low maintenance
- 4-1/2" in diameter by 1-1/2" in height
- Compact size allows the sampling device to be located near filling processes where space is limited
- Reports accurately the air quality near fill areas and reduce false positives from operators
- Can be easily and aseptically connected to the desired points of sample by use of sterile 3/8" PVC tubing
- Connections are made from the top orifice of the SMA Compressed Air Atrium directly to regulated compressed air/gas locations
- Has a flow rate of 1 to 2 CFM
- Tested and validated to achieve a 95% capture efficiency
- Exhaust air is released from underneath the unit directly to the environment without affecting the sample in progress
- Uses a 100mm plate with a media fill of 25mL (standard from most suppliers)
- The 25mL fill allows the user the ability to sample up to 90 cubic feet on one agar plate
- Air flow regulation can be accomplished either by the installation of a pressure regulator valve at point of sample or by use of the SMA-ROT-SS Rotameter
  - The SMA-ROT-SS Rotameter is attached to the compressed air line prior to sampling and flow regulated from the petcock valve of the compressed air/gas line
  - Once flow is regulated the unit is removed and replaced with the SMA-CA Atrium
- Assures direct testing of air/gas from the compressed air line to the SMA CA Sampler without the intrusion of the metering device

SMA™ PORTABLE COMPRESSED AIR SAMPLER

FEATURES:

- Adds calibrated flow and timing features to sampling compressed air/gas line
- Made of mirror-finished 316 Stainless Steel
- Incorporates a 4 hour continuous operation battery that can be recharged in 45 minutes
- Simply connecting a compressed air line to the top of the unit can reduce pressure and assure a 1 CFM (28.3LPM) flow rate

SMA-316-CA-25	316 Stainless CA 25 mL fill level
SMA-ROT-SS	Stainless Steel Rotameter
SMA-ROT-STD	Rotameter Stand
SMA-CA200	SMA Portable Compressed Air Sampler
SMA-CA200-500	Additional Sampling Head

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

SMA Compressed Air Validation Report
SMA Atrium User Manual

SMA™ MULTI LOCATION CONTROL CENTERS

The SMA Control Centers are available in two models: The “EX Model” Control Center requires the end user to supply a vacuum source either from a central vacuum system or a separate vacuum pump. The “CC Model” Control Center is designed and supplied with an external pump (exception is the SMA-CC-1 that incorporates an internal pump). The SMA Control Centers provide calibrated flow regulation, timing and the ability to connect the VAI OneTouch, Command System Accessory. The following are brief descriptions of the available SMA Control Centers. (Available in 115V or 220VAC).

SMA-EX-1 FEATURES:

- Designed for use with central vacuum systems or external pumps
- Incorporates 1 rotameter, 1 programmable (memory) timer and a solenoid in a 304L Stainless Steel cabinet
- 8" long by 8" wide by 6" high
- Ensures the integration of calibrated time and flow
- Runs for a specified time period, then automatically turns off the vacuum to the SMA Atrium

SMA-CC-1 FEATURES:

- Designed for use as a stand alone unit
- Incorporates 1 rotameter, 1 programmable (memory) timer, and a 1/6 HP pump in a 304L Stainless Steel cabinet
- 16” long by 12” wide by 8 1/2” high
- Ensures the integration of calibrated time and flow
- Runs for a specified time period, then automatically turns off the vacuum to the SMA Atrium

SMA-EX-2 (no pump) and SMA-CC-2 (includes pump) FEATURES:

- Enables 2 location testing simultaneously or independently
- Incorporates 2 rotameters and 2 programmable (memory) timers in a 304L Stainless Steel cabinet
- 16" long by 12" wide by 8 1/2" high
- Ensures the integration of calibrated time and flow
- Runs for a specified time period, then automatically turns off the vacuum to the SMA Atrium
- Timers run independently from each other while utilizing a common vacuum source
- SMA-CC-2 includes a 3/4 HP pump

SMA-EX-3 (no pump) and SMA-CC-3 (includes pump) FEATURES:

- Enables 3 location testing simultaneously or independently
- Incorporates 3 rotameters and 3 programmable (memory) timers in a 304L Stainless Steel cabinet
- 10" long by 12" wide by 10” high
- Ensures the integration of calibrated time and flow
- Runs for a specified time period, then automatically turns off the vacuum to the SMA Atrium
- Timers run independently from each other while utilizing a common vacuum source
- SMA-CC-3 includes a 3/4 HP pump

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SMA-EX-5 (no pump) SMA-CC-5 (includes pump) FEATURES:

- Enables 5 location testing done simultaneously
- Incorporates 5 rotameters, 1 programmable (memory) timer and 1 solenoid in a 304L Stainless Steel cabinet
- 12" long by 17" wide by 8-1/2" high
- Ensures the integration of calibrated time and flow
- Runs for a specified time period then automatically turns off the vacuum to the SMA Atrium
- Timers run independently from each other while utilizing a common vacuum source
- SMA-CC-5 includes a 1-1/2 HP pump

SMA-EX-5-5 (no pump) SMA-CC-5-5 (includes pump) FEATURES:

- Enables 5 location testing done simultaneously or independently
- Incorporates 5 rotameters and 5 programmable (memory) timers in a 304L Stainless Steel cabinet
- 12" long by 17" wide by 8-1/2" high
- Ensures the integration of calibrated time and flow
- Runs for a specified time period then automatically turns off the vacuum to the SMA Atrium
- Timers run independently from each other while utilizing a common vacuum source
- The choice for setup of a OneTouch System

SMA-CC-10 (includes pump) FEATURES:

- Enables 10 location testing simultaneously or independently
- Incorporates 10 rotameters, 10 programmable (memory) timers and 10 solenoids in a 304L Stainless Steel cabinet
- 23” long by 28” wide by 22” high
- Ensures the integration of calibrated time and flow
- Runs for a specified time period then automatically turns off the vacuum to the SMA Atrium
- Timers run independently from each other while utilizing a common vacuum source
- SMA-CC-10 includes a 5 HP pump
- Designed to be integrated with the OneTouch System requiring remote location of the control center and pump

Order#	Atrium Description
SMA-EX-1	1 Location EX (without pump) Control Center
SMA-EX-2	2 Location EX (without pump) Control Center
SMA-EX-3	3 Location EX (without pump) Control Center
SMA-EX-5	5 Location EX (without pump) Control Center with timer
SMA-EX-5-5	5 Location Independent Control Center (without pump)
SMA-CC-1	1 Location CC Control Center with Internal pump
SMA-CC-2	2 Location CC Control Center with External pump
SMA-CC-3	3 Location CC Control Center with External pump
SMA-CC-5	5 Location CC Control Center with timer and External pump
SMA-CC-5-5	5 Location Independent Control Center with Pump
SMA-CC-10	10 Location CC Control Center with External pump
SMA-VPS-02	Vacuum Pump Center for CC-1 thru CC-5
SMA-CC-INTF-5	SMA OneTouch Interface Module for 5 Location
SMA-CC-INTF-10	SMA OneTouch Interface Module

Interface Module

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

SMA Atrium Validation Report
SMA Control Center User Manual

SMA WIRELESS CONTROL PANELS

The SMA Wireless Control Panels utilize FHSS (Frequency Hopping Spread Spectrum) Integrated radio with digital I/O's and signals making it ideal for harsh industrial environments.

Features:

- No FCC license required. Complies with Part 15 of FCC rules.
- Reliable communication in high EMI/RFI short or long range
- Suitable for installation in today's market as well as in the future – even as band use increases
- Eliminates conduits and cables
- Easy to use, no-setup or programming
- Controls and alarms for the individual ports are similar to the OT-04 control panels offered by VAI
- Start a Sample Cycle
- Abort a Sample Cycle
- Monitor a sample cycle in progress
- Audio alarm and visual lamp to notify User Sample Cycle is complete
- Audio alarm and visual lamp notifies User the Vacuum Preset is missing or not up to the required amount necessary for the Sample Cycle
- Audio alarm and visual lamp will enable when an individual port does not have the calibrated Air Flow required for sampling
- Timer in the panel will indicate time elapsed during Sample Cycle
- Sample Cycle
- Sample Cycle duration can be programmed at the Controller or Panel Timer in the clean room
- 1 CFM/30LM error detection is available
- Can control one to ten ports depending on the customers needs

Order#	Description
SMA-OT-AL-101A/B*	Controls and monitors one port
SMA-OT-WL-102A/B*	Controls and monitors two ports
SMA-OT-WL-103A/B*	Controls and monitors three ports
SMA-OT-WL-105A/B*	Controls and monitors five ports

** A=Controller timer is Master, B=Timer in clean room is Master*

SMA ONETOUCH™ COMMAND SYSTEM

OneTouch, Command System FEATURES:

- Removes all electronics and vacuum pumps from the aseptic area
- Requires only the OneTouch Remote Start Module and the SMA Atrium to be placed in the aseptic area; all other components are placed remotely
- Requires hard wiring of both the vacuum tubing and electronic plenum wiring for the OneTouch Point of Sample boxes
- Works with VAI's integrated computer software database that enables the data transfer of time of sample, sample date, length of sample, sample location, entry results and other features directly to your computer system
- Utilizes the SMA Atrium and one of the SMA Control Centers
- Adds to the Control Center features by using the OneTouch Point of Sample Box and the OneTouch Facility Control Module that remotely starts the sampling and eliminates the need to access the control center

OneTouch Point of Sample Box FEATURES:

- Begins sampling at the desired location of the SMA Atrium
- 4" long by 3" wide by 3" high
- Contains a system ready light, a sample completion light and a reset/operate button
- 316L #4 brush finished Stainless Steel completely sealed cabinet for disinfection purposes
- Signals back to the control center to begin sampling upon user prompting
- Set on surfaces or hard wired to a suitable mounting location on walls, in benches or within the isolator

OneTouch Facility Control Module FEATURES:

- Available in either modular or flush mount units
- Can be attached or flush mounted to desired wall locations and can remotely control sampling
- Can be used to view where in the facility sampling is being conducted

Additional FEATURES of the SMA-04 series: xx may be 1,2,3 or 5

- Start Sample Cycle
- Abort Sample Cycle
- SMA-OT-04 10xxA, Model A, the timer in the SMA Controller determines the length of time the sample cycle takes. Model SMA-OT-04-10xxB has the same functionality as the SMA-OT-04 A with the timing duration controlled by the timer in the SMA-OT-04 unit. The selection of timing control is determined by the user and programmed at the factory. Hardware of the SMA-OT-04 models A or B is exactly the same.
- Vacuum Present error will emit an audio tone and a flashing error lamp when a vacuum is not present during a sample cycle.

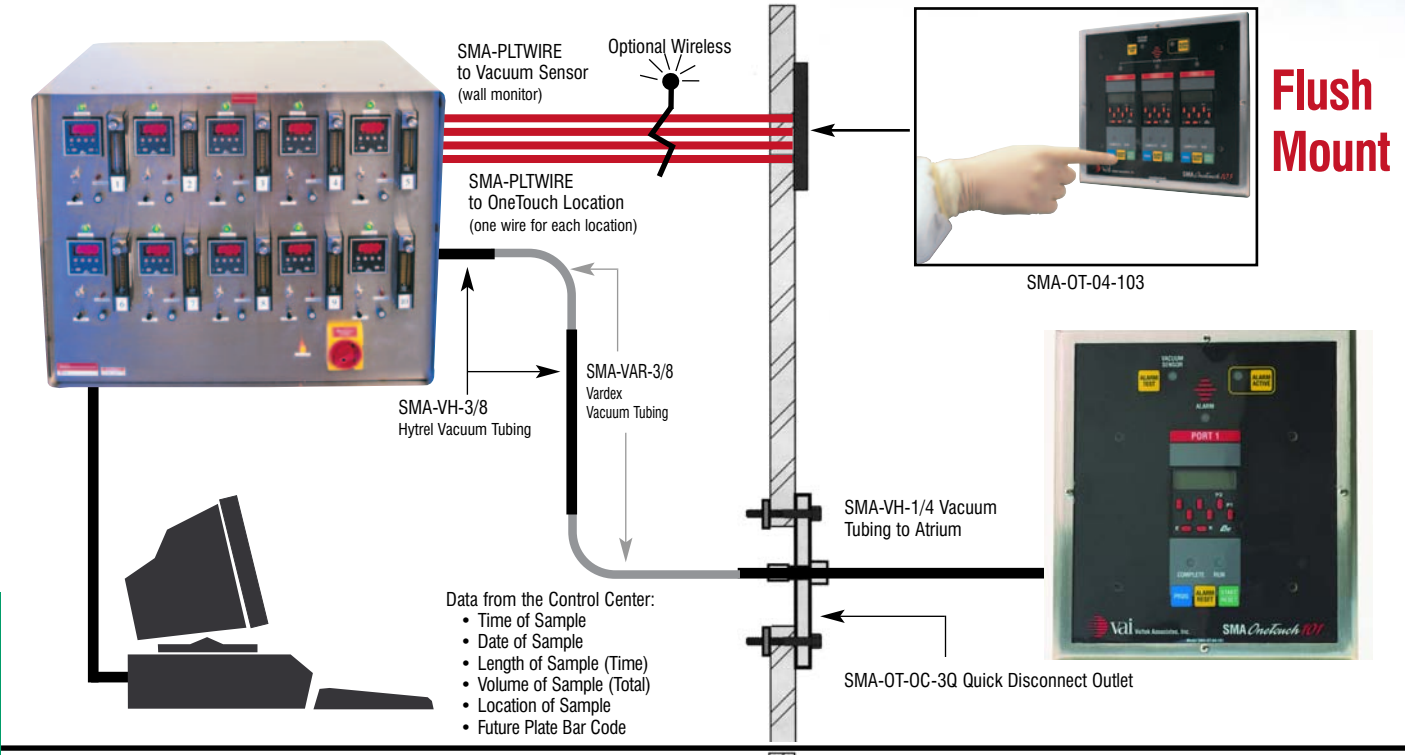
Order#	OneTouch Component Description
SMAOT-01-# of Locations	SMA OneTouch Modular Wall Control Box
SMAOT-02	SMA OneTouch Point of Sample Box
SMAOT-04-(1,2,3,5, or 10) A or B	SMA OneTouch Soft Touch Modules 1, 2, 3, 5, or 10 location
SMA-PLTWIRE	Plenum Wiring (ordered and priced per foot)
SMA-VH (1/4" or 3/8")	HYTREL Vacuum Tubing (ordered and priced per foot)
SMA-OT-OC-1	Single Stainless Outlet Cover w/ Fittings (Penetration Kit #1)
SMA-OT-OC-2	Dual Stainless Outlet Covers w/ Fittings (Wall Cavity Adapter Kit #2)
SMA-OT-OC-3	Vacuum Outlet Cover w/ Fittings (Kit #3Q, #3P or #3B)
SMA-ILR-01	Stainless Steel Rotameter for flush mount inline system w/out quick disconnect
SMA-ILR-02	Stainless Steel Rotameter for inline system w/quick disconnect
SMA-ILR-03	Stainless Steel Rotameter for flush mount inline system w/ quick disconnect

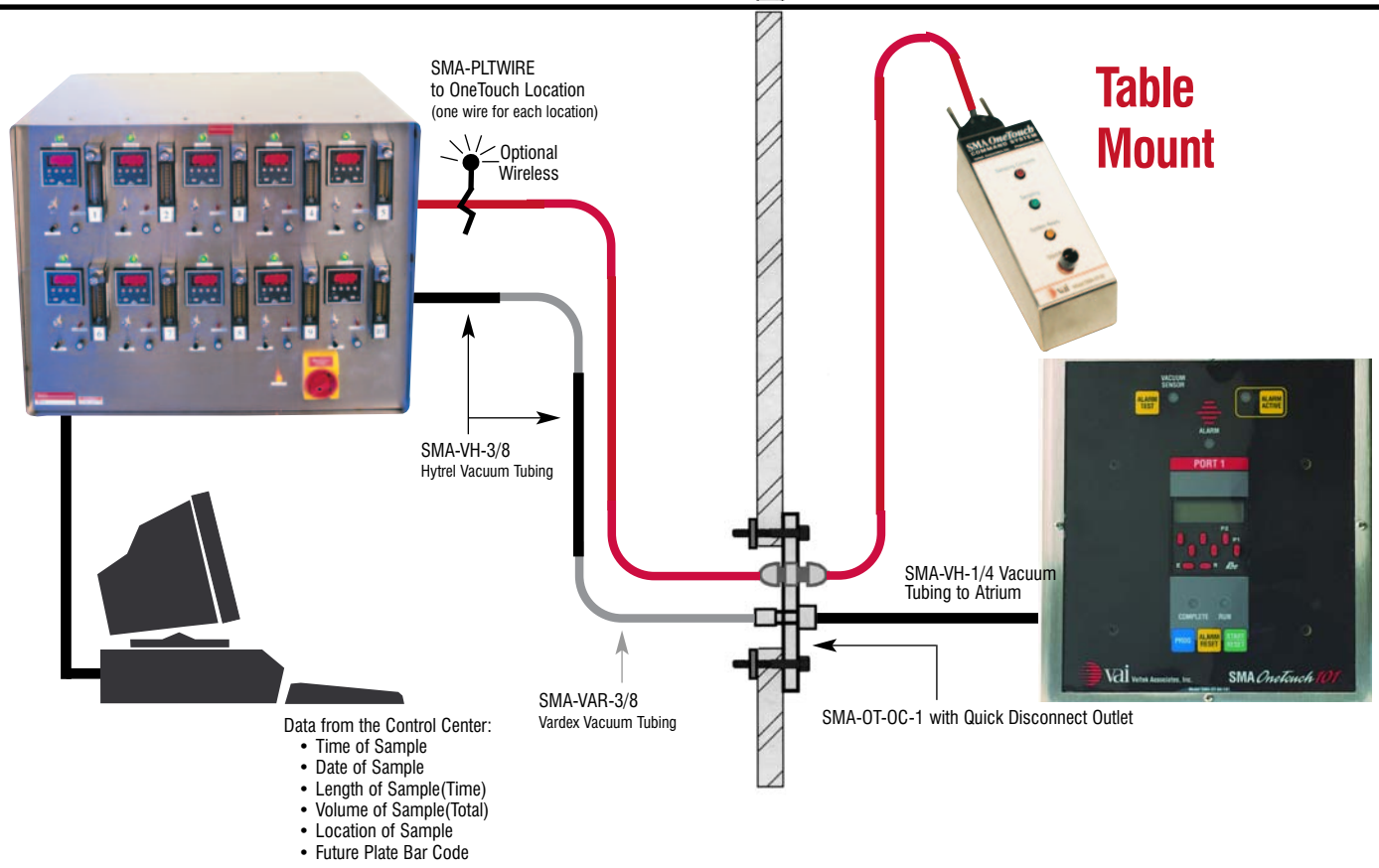
AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

SMA Atrium Validation Report
SMA Control Center User Manual

SMA ONETOUCH™ COMMAND SYSTEM

MICROBIAL AIR SAMPLING SYSTEM



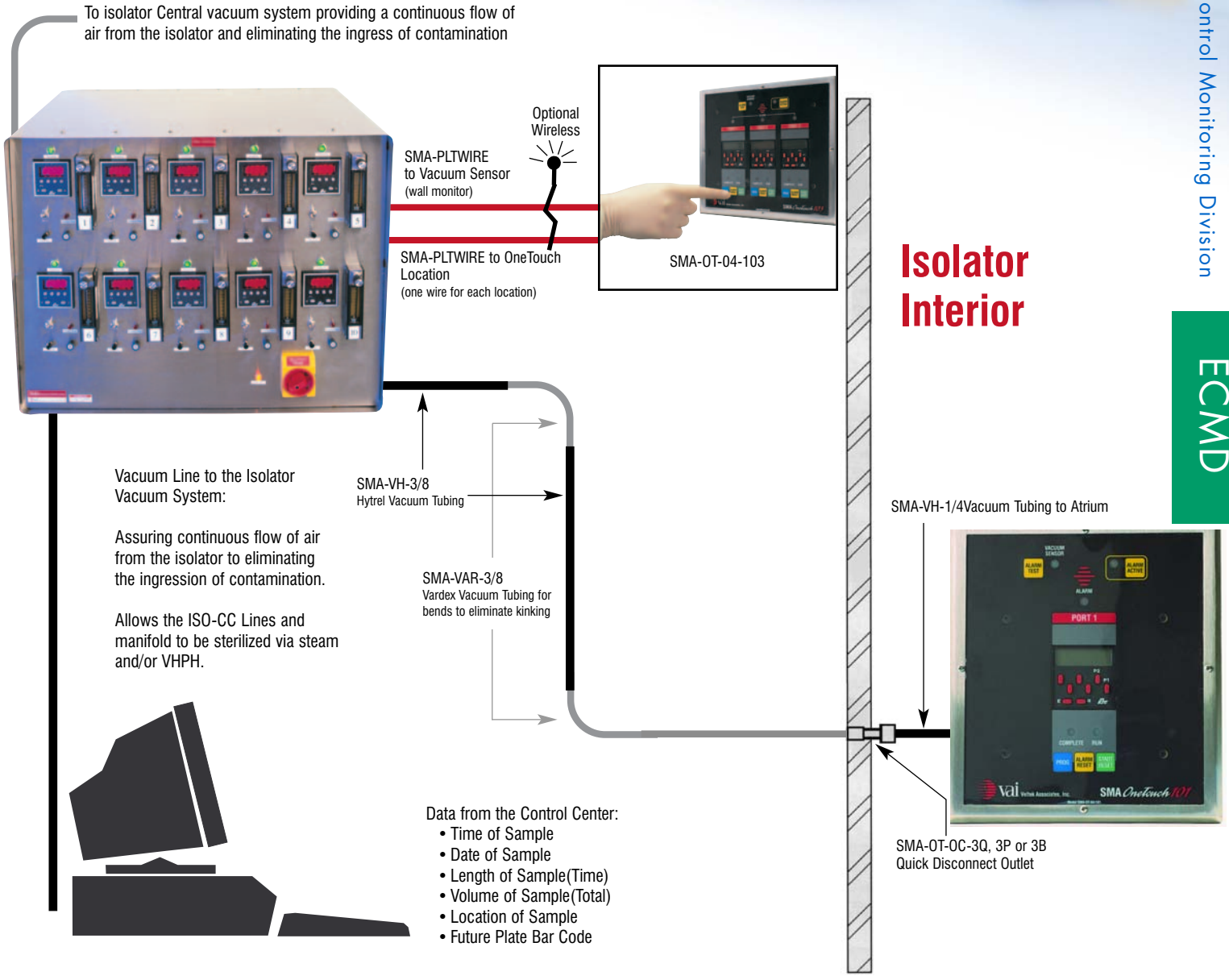


SMA ONETOUCH™ COMMAND SYSTEM

ISO-CC

Microbial Air Sampling System – ISO-CC

The SMA OneTouch System removes electronic devices from the area. Within the area is only a flush mount or table top start module and an SMA Atrium that is connected by 1/4" ID tubing to a stainless steel quick disconnect outlet cover on the wall.


To isolator Central vacuum system providing a continuous flow of air from the isolator and eliminating the ingress of contamination
Optional Wireless
SMA-PLTWIRE to Vacuum Sensor (wall monitor)
SMA-PLTWIRE to OneTouch Location (one wire for each location)
SMA-OT-04-103
Isolator Interior
Vacuum Line to the Isolator Vacuum System:
Assuring continuous flow of air from the isolator to eliminating the ingression of contamination.
Allows the ISO-CC Lines and manifold to be sterilized via steam and/or VHPH.
SMA-VH-3/8 Hytrel Vacuum Tubing
SMA-VAR-3/8 Vardex Vacuum Tubing for bends to eliminate kinking
SMA-VH-1/4Vacuum Tubing to Atrium
Data from the Control Center:
• Time of Sample
• Date of Sample
• Length of Sample(Time)
• Volume of Sample(Total)
• Location of Sample
• Future Plate Bar Code
SMA-OT-OC-3Q, 3P or 3B Quick Disconnect Outlet

SMA™ ISO-CC MICROBIAL AIR SAMPLER

The SMA-ISO feature is an adaptation done to the CC-1, CC-2, CC-3, CC-5 and CC-10 Control Centers. The system design permits the highest level of confidence for sampling within the isolator and assures the non-aspiration or return of possible contaminants from the exterior environment to the isolator or barrier unit. All CC units can be adapted to operate in the ISO mode.

FEATURES:

- Integrates a 3 way solenoid between the rotameter and the SMA Atrium providing an automatic switching of air flow at the completion of sampling from the SMA Control Center to the isolator vacuum system
- The timer samples from the Atrium through the solenoid to the rotameter (where volume is gauged) and then proceeds to the control center vacuum pump
- Once sampling is complete the timer signals the solenoid to switch the air flow direction to the isolators central vacuum system
- Ensures the air is always being pulled from the isolator either in a sampling condition or a pause position directing the air flow to the isolator vacuum system
- Prevents the return of air into the isolator as flow is always being pulled outward
- Delivered ready to use with all the solenoids contained within the control center
- Allows continuous sampling to be conducted (up to 3 hours) on one agar plate

SPECIFICATIONS:

- Air Flow: 1 CFM
- Air Flow Accuracy: +/- 5%
- Maximum Sample Volume: 999.99 CFM
- Maximum Temperature through Solenoids: 480oF
- Connections from Control Center to Atrium: 1/4" NPT
- Connection to Isolator Vacuum System: 1/4" NPT
- Connections from CC to Pump: SMA-CC-2 (3/8" ID); SMA-CC-3 & 5 (1/2" ID); SMA-CC-10 (1-1/4" IS)
- Voltage (CC): 115V AC or 220V AC
- Amps: 15A
- Calibration: Annual
- OneTouch Ready: Yes

Order#	ISO-CC Component Description
SMA-CC-1I	1 Location Control Center w/internal pump
SMA-CC-2I	2 Location Control Center w/external pump
SMA-CC-3I	3 Location Control Center w/external pump
SMA-CC-5I	5 Location Control Center w/external pump
SMA-CC-5-5I	5 Location Independent Control Center
SMA-CC-10I	10 Location Control Center w/external pump

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

SMA Atrium Validation Report
SMA Control Center User Manual

SMA™ MICROPORTABLE VIABLE AIR SAMPLER

The SMA MicroPortable is a rechargeable battery operated microbial air sampler for determining the level of existent viable contaminates in their aseptic manufacturing operations.

FEATURES:

- Designed of 316L mirror-finished Stainless Steel
- Calibrated air flow
- Digital readout in cubic feet per minutes or liters
- 1 CFM (28.3LPM) and/or 5 CFM (141.5LPM) flow rates
- Dual user preset sampling volumes
- Utilizes the SMA Atrium top that can be completely sterilized via steam, heat or ETO
- 10" high by 6" wide
- 12 pounds
- 8 hour continuous operation without need for recharging
- 45 minute recharge time
- Can operate while recharging
- Uses a media fill level of 25mL (standard from most supplier)
- Can be located near filling processes or located remotely with the incorporation of the remote sampling probe that can be sterilized prior to use
- Designed to provide a tortuous path that air must travel, which assures a 95% capture efficiency of 0.5 micron particles and larger
- Integration of a multi-orifice top or remote sampling probe provides the ability to sample for over 120 cubic feet without agar desiccation
- Measures either CFM or Liters dependent upon model chosen
- Preset volumes can be programmed and stored into the memory of the counter from 1 cubic foot or liter to 999 cubic feet or liters
- Recall feature of programmed user preset volumes assures future sampling is done without the need to re-enter sample volumes

Order#	MicroPortable Description
SMAP-191-03-CFM or Liter	Lightweight portable, Delran top & bottom, lightweight stainless steel case & Softouch controls.
SMA-P201-03	Stainless steel unit & Softouch controls
SMA-P300-03	Hazard Safe, Softouch , Stainless steel; explosion proof UN1604
SMA-316-TO-25-1/4	Additional SMA Multi-Orifice Sampling Head
SMA-316-RE-PROBE	Additional SMA Remote Probe Sampling Head
SMA-191-BC-CE-01	Battery Recharger for P191, P201 and P300 (110 V AC)
SMA-191-BC-CE-02	Battery Recharger for P191, P201 and P300 (220 V AC)
SMA-504	Carrying Case
SMA-506	Disposable Dust Covers (10)
SMA-600	SMA MicroPortable 316L Stand

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

SMA MicroPortable Validation Report
SMA MicroPortable User Manual

"How To Purchase An SMA System"

Decide whether the SMA will be installed in a controlled environment or isolator.

CC-Control Centers provide calibrated flow regulation, timing and the ability to connect the VAI OneTouch, Command System Accessory.

ISO-CC-system design permits the highest level of confidence for sampling within the isolator and assures the non-aspiration or return of possible contaminants from the exterior environment to the isolator or barrier unit.

Attain a facility or area map.

Mark where sampling is intended to be done.

Choose a control center that meets the present and future needs of your operation.

Decide where to locate the control center.

See Pages 94-95

Can be located 125 ft from the cc location insert chart for each CC distances can be increased from the above. Please contact VAI Tech. support for details

Decide which Atrium(s) fit your needs.

multi-orifice-test method most recognized by organizations for determining the level of existent microbial contaminants in their manufacturing operations

See Page 91

remote-designed with a single extension tube to fit into tight locations deemed critical to be tested for microbial contaminants

See Page 92

Choose which atrium fill level meets your needs.

- 32 ml — up to 3 hrs of sampling
- 25 ml — up to 1.5 hrs of sampling
- 18 ml — up to 50 minutes of sampling

Choose which Atrium top orifice size meets your needs.

See Page 91

- 32 ml — for up to 3 hrs of testing
- 25 ml — for up to 1 hr of testing
- 18 ml — for 50 minutes of sampling

Decide how you wish to start the unit and where the start modules will be located.

- Flush Mount Wall Module
- Table Mount
- Control Center

Decide if you will require an in-line rotameter. If so, decide on the locations.

Measure distances and determine the amount of Hytrel/vardex tubing that will be needed. Do the same for the plenum wires for the OT boxes

Do you need VAI installation? (Recommended)

SMA™ ATRIUM-STAINLESS STEEL

Order#	Atrium Description
SMA-316-18-1/2	Complete Atrium 316 Stainless Steel SMA 18 ml. fill
SMA-316-T-18-1/2	316 Stainless Steel SMA 18 ml. fill Top Only
SMA-316-18-1/4	Complete Atrium 316 Stainless Steel SMA 18 ml. fill
SMA-316-T-18-1/4	316 Stainless Steel SMA 18 ml. fill Top Only
SMA-316-25-1/2	Complete Atrium 316 Stainless Steel SMA Unit 25 ml. fill 1/2'
SMA-316-T-25-1/2	316 Stainless Steel SMA 25 ml. fill Top Only
SMA-316-25-1/4	Complete Atrium 316 Stainless Steel SMA Unit 25 ml. fill
SMA-316-T-25-1/4	316 Stainless Steel SMA 25 ml. fill Top Only
SMA-316-32-1/2	Complete Atrium 316 Stainless Steel SMA Complete Unit 32 ml. fill 1/2'
SMA-316-T-32-1/2	316 Stainless Steel SMA 32 ml. fill Top Only
SMA-316-32-1/4	Complete Atrium 316 Stainless Steel SMA Complete Unit 32 ml. fill 1/4'
SMA-316-T-32-1/4	316 Stainless Steel SMA 32 ml. fill Top Only
SMA-316-B	Atrium Bottom 316 Stainless Steel SMA Bottom Bottom Only NA
SMA-316-B-ORIFICE	Atrium Bottom 316 Stainless Atrium Bottom Orifice OPEN
SMA-316-B-SC	Atrium Bottom 316 SS SMA Bottom for SMA-WALLATR Bottom Only WALL NA
SMA-316-CA-18	Complete Atrium 316 Stainless Steel Comp. Air 18 ml. fill
SMA-316-CA-25	Complete Atrium 316 Stainless Steel Comp. Air Complete Unit 25 ml. fill
SMA-316-CA-32	Complete Atrium 316 Stainless Steel Comp. Air Complete Unit 32 ml. fill
SMA-316-LO-15	Additional Limiting Orifice 15 inches VAC Additional Limiting Orifice 15 inches VAC Per each
SMA-316-LO-18	Additional Limiting Orifice 18 inches VAC Additional Limiting Orifice 18 inches VAC Per each
SMA-316-RE-18	Complete Atrium 316 Stainless Steel REMOTE SMA 18 ml. fill
SMA-316-RE-18-OB	Complete Atrium 316 Stainless Steel REMOTE SMA 18 ml. fill Complete Unit One piece bottom
SMA-316-RE-25	Complete Atrium 316 Stainless Steel REMOTE SMA Complete Unit 25 ml. fill
SMA-316-RE-25-OB	Complete Atrium 316 Stainless Steel REMOTE SMA Complete Unit One piece bottom 25 ml. fill
SMA-316-RE-32	Complete Atrium 316 Stainless Steel REMOTE SMA Complete Unit 32 ml. fill
SMA-316-RE-32-OB	Complete Atrium 316 Stainless Steel REMOTE SMA Complete Unit One Piece Bottom 32 ml. fill
SMA-316-RE-PROBE-18	Probe for MicroPortable (17'in length and 18 ml). Requires the Connective Top Arrangement SMA MicoPortable Probe 17' in length 18 ml.
SMA-316-RE-PROBE-25	Probe for MicroPortable (17'in length and 25 ml.) Requires the Connective Top Arrangement SMA MicoPortable Probe 17' in length 25 ml.
SMA-316-RE-TO-18	Atrium Top 316 Stainless Steel REMOTE Top 18 ml. fill Top Only
SMA-316-RE-TO-25	Atrium Top 316 Stainless Steel REMOTE 25 ml. fill Top Only
SMA-316-RE-TO-32	Atrium Top 316 Stainless Steel REMOTE 32 ml. fill Top Only
SMA-316-SCREW	Relpacement Atrium Bottom Screws 100/bag Replacement Atrium Bottom Screws NA

SMA™ ATRIUM-ANODIZED ALUMINUM

Order#	Atrium Description
SMA-AA-18-1/2	Complete Atrium Anodized Aluminum SMA 18 ml. fill 1/2'
SMA-AA-18-1/4	Complete Atrium Anodized Aluminum SMA 18 ml. fill 1/4'
SMA-AA-25-1/2	Complete Atrium Anodized Aluminum SMA 25 ml. fill 1/2'
SMA-AA-25-1/4	Complete Atrium Anodized Aluminum SMA 25 ml. fill 1/4'
SMA-AA-32-1/2	Complete Atrium Anodized Aluminum SMA 32 ml. fill 1/2'
SMA-AA-32-1/4	Complete Atrium Anodized Aluminum SMA 32 ml. fill 1/4'
SMA-AA-B	Atrium Bottom Anodized Aluminum SMA
SMA-AA-T-18-1/2	Atrium Top Anodized Aluminum SMA 18 ml. fill 1/2'
SMA-AA-T-18-1/4	Atrium Top Anodized Aluminum SMA 18 ml. fill 1/4'
SMA-AA-T-25-1/2	Atrium Top Anodized Aluminum SMA 25 ml. fill 1/2'
SMA-AA-T-25-1/4	Atrium Top Anodized Aluminum SMA 25 ml. fill 1/4'
SMA-AA-T-32-1/2	Atrium Top Anodized Aluminum SMA 32 ml. fill 1/2'
SMA-AA-T-32-1/4	Atrium Top Anodized Aluminum SMA 32 ml. fill 1/4'
SMA-WALLATR	Bracket Only Requires SMA-316-B-SC Atrium Bracket Use with SC Bottom

SMA™ MICROPORTABLE VIABLE AIR SAMPLER

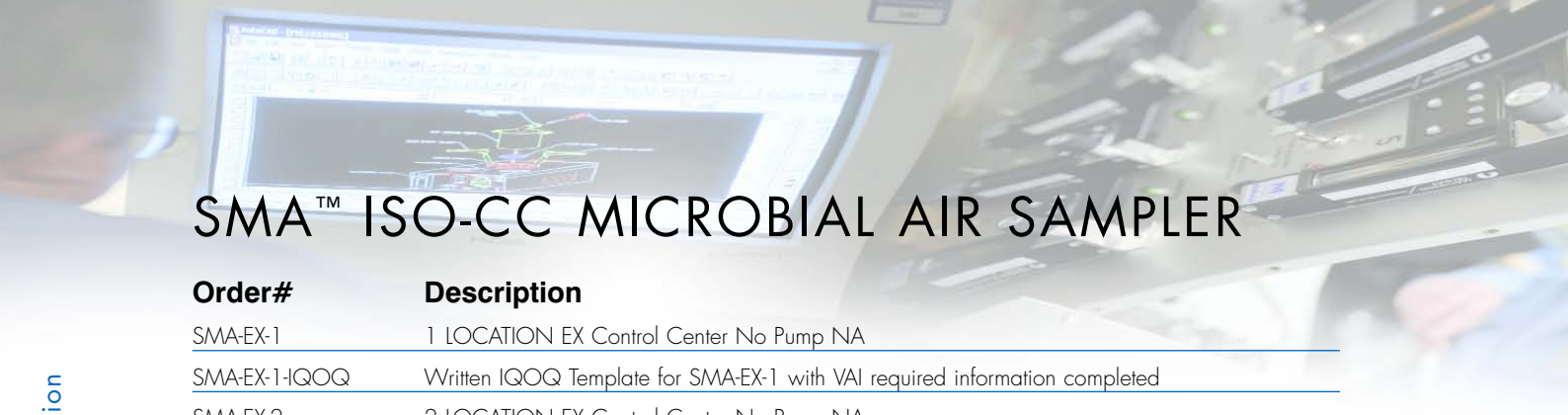
Order#	Description
SMA-503-110	Optional P100/200 110V Additional Recharger Portable Option NA
SMA-503-220	Optional P100/200 220V Additional Recharger Portable Option NA
SMA-504	Optional P100/200 Carrying Case Portable Option NA
SMA-506	Optional P100/200 Disposable Dust Covers (10) Portable Option NA
SMA-600	SMA Microportable Stand
SMA-601	Portable Stand (IV) Type w/Flay Top
SMA-603	P100-200-300 Calibration Flow Tube Assembly
SMA-P100-200-IQOQ	Written IQOQ Template for SMA P100 or P200 with VAI required information completed
SMA-P100-BC-220-CE	Optional P100/200 220V Additional Recharger Portable Option NA
SMA-P191-03	Lightweight portable, Delran Top and Bottom, Lightweight Stainless Casing and Soft Touch Controls
SMA-P191-BATTERY	P191 and P201 Additional Rechargeable Battery
SMA-P201-03	Stainless Steel Unit and Soft Touch Controls
SMA-P300-03	Hazardous Soft Touch Stainless Steel Explosion Proof UN 1604
SMA-PCAL-01	MicroPortable Air Flow Calibration Tube Assembly

SMA™ COMPRESSED AIR SAMPLER

Order#	Description
SMA-CA-502	Additional Braided Stainless Pressure Hose to fit CA200
SMA-CA200	Portable Battery Operated Compressed Air Sampler Compressed Air 115v or 220v
SMA-CA200-500	Portable Battery Operated Compressed Air Sampler Compressed Air Top
SMA-CA200-501	Portable Battery Operated Compressed Air Sampler Compressed Air 'O' Ring Gasket
SMA-CA200-IQOQ	Written IQOQ Template for SMA-CA200 with VAI required information completed

SMA™ MULTI LOCATION CONTROL CENTERS

Order#	Description
SMA-CC-001-F	Filter CC-1 SMA CC-1
SMA-CC-002-F	Filter CC-2 thru CC-5 SMA CC-2 thru CC-5 Filter
SMA-CC-003-F-CE	Filters for the Leybold CE pump
SMA-CC-1	1 LOCATION CC Contro1 Center Includes Pump NA
SMA-CC-1-IQOQ	Written IQOQ Template for SMA-CC-1with VAI required information completed
SMA-CC-1-PUMP	Additional Pump for the SMA-CC-1 SMA-CC-1 Pump Gast Model 3032-101A-G609X
SMA-CC-10	10 Port Control Center with Pump. 208 VAC Includes 5 HP vacuum Pump
SMA-CC-10-IQOQ	Written IQOQ Template for SMA-CC-10 with VAI required information completed
SMA-CC-10-PUMP	Additional Pump for the SMA-CC-10 SMA-CC-10 Pump
SMA-CC-10-SHIELD	10 Port Control Center Plexiglass shield
SMA-CC-10I	10 LOCATION ISO-CC Control Center Min 208 V AC Includes Pump Min 208 V AC
SMA-CC-2	2 LOCATION CC Control Center Includes Pump NA
SMA-CC-2-IQOQ	Written IQOQ Template for SMA-CC-2 with VAI required information completed
SMA-CC-2/3-PUMP	Additional Pump for the SMA-CC-2 & 3 SMA-CC-2/3 Pump
SMA-CC-3	3 LOCATION CC Control Center Includes Pump NA
SMA-CC-3-IQOQ	Written IQOQ Template for SMA-CC-3 with VAI required information completed
SMA-CC-5	5 LOCATION CC Control Center Includes 1.5 HP Pump NA
SMA-CC-5-5	5-5 LOCATION CC Control Center Includes 1.5 HP Pump NA
SMA-CC-5-5-IQOQ	Written IQOQ Template for SMA-CC-5-5 with VAI required information completed
SMA-CC-5-5-SHIELD	CC-5-5 Port Control Center Plexiglass shield
SMA-CC-5-5I	5-5 LOCATION ISO-CC Control Center Includes 1.5 HP Pump NA
SMA-CC-5-IQOQ	Written IQOQ Template for SMA-CC-5 with VAI required information completed
SMA-CC-5-ISO-IQOQ	Written IQOQ Template for SMA-CC-5 ISO-CC with VAI required information completed
SMA-CC-5-SHIELD	5 Port Control Center Plexiglass shield
SMA-CC-CART	Stainless Steel Cart for the SMA-CC-1 thru SMA CC-5
SMA-CC-STAND	Rotameter Stand Rotameter For Matheson FM1000
SMA-VAR-3/8	Vardex Tubing 3/8' ID for Bends Tubing Sold Per Foot NA
SMA-VH-1/4	Hytrel Bevaline Tubing 1/4' ID Tubing Sold Per Foot NA
SMA-VH-3/8	Hytrel Bevaline Tubing 3/8' ID Tubing Sold Per Foot NA
SMA-VPS-01-10	Vaccum Pump Switcher for CC-10 Vaccum Pump Switcher
SMA-VPS-02	Vaccum Pump Sensor for CC-1 thru CC-5 Vaccum Pump Sensor



SMA™ ISO-CC MICROBIAL AIR SAMPLER

Order#	Description
SMA-EX-1	1 LOCATION EX Control Center No Pump NA
SMA-EX-1-IQOQ	Written IQOQ Template for SMA-EX-1 with VAI required information completed
SMA-EX-2	2 LOCATION EX Control Center No Pump NA
SMA-EX-2-IQOQ	Written IQOQ Template for SMA-EX-2 with VAI required information completed
SMA-EX-3	3 LOCATION EX Control Center No Pump NA
SMA-EX-3-IQOQ	Written IQOQ Template for SMA-EX-3 with VAI required information completed
SMA-EX-5	5 LOCATION EX Control Center No Pump NA
SMA-EX-5-5	5-5 LOCATION CC Control Center without pump
SMA-EX-5-IQOQ	Written IQOQ Template for SMA-EX-5 with VAI required information completed
SMA-CC-1-ISO-IQOQ	Written IQOQ Template for SMA-CC-1 ISO CC with VAI required information completed
SMA-CC-10-ISO-IQOQ	Written IQOQ Template for SMA-CC-10 ISO CC with VAI required information completed
SMA-CC-1I	1 LOCATION ISO CC Control Center Includes Pump
SMA-CC-2-ISO-IQOQ	Written IQOQ Template for SMA-CC-2 ISO CC with VAI required information completed
SMA-CC-2I	2 LOCATION ISO CC Control Center Includes Pump
SMA-CC-3-ISO-IQOQ	Written IQOQ Template for SMA-CC-3 ISO CC with VAI required information completed
SMA-CC-3I	3 LOCATION ISO CC Control Center Includes Pump
SMA-CC-5-51-ISO-IQOQ	Written IQOQ Template for SMA-CC-5-5 ISO CC with VAI required information completed
SMA-CC-5-51	5-5 LOCATION ISO CC Control Center Includes Pump
SMA-CC-5-ISO-IQOQ	Written IQOQ Template for SMA-CC-5 ISO CC with VAI required information completed
SMA-CC-51	5 LOCATION ISO CC Control Center Includes Pump

SMA™ ONETOUCH CONTROL SYSTEM

Order#	Description
SMA-CC-INTF-10	SMA OneTouch Interface Module For CC-10
SMA-OT-01-#	OneTouch Wall Monitor OneTouch Wall Box NA
SMA-OT-02	OneTouch Table Mount Box OneTouch Box Rubber Feet
SMA-OT-03-0	Replacement OneTouch Module All SMA-OT-03 Units
SMA-OT-03-1	Flush Monitor 1 Location OneTouch Wall Monitor
SMA-OT-03-10	Flush Monitor 10 Location OneTouch Wall Monitor
SMA-OT-03-2	Flush Monitor 2 Location OneTouch Wall Monitor
SMA-OT-03-3	Flush Monitor 3 Location OneTouch Wall Monitor
SMA-OT-03-4	Flush Monitor 4 Location OneTouch Wall Monitor
SMA-OT-03-5	Flush Monitor 5 Location OneTouch Wall Monitor
SMA-OT-03-6	Flush Monitor 6 Location OneTouch Wall Monitor
SMA-OT-04-101	Flush Monitor 1 Location SoftTouch OneTouch Wall Monitor
SMA-OT-04-1010	Flush Monitor 10 Location SoftTouch OneTouch Wall Monitor
SMA-OT-04-102	Flush Monitor 2 Location SoftTouch OneTouch Wall Monitor
SMA-OT-04-103	Flush Monitor 3 Location SoftTouch OneTouch Wall Monitor

SMA-OT-04-104	Flush Monitor 4 Location SoftTouch OneTouch Wall Monitor
SMA-OT-04-105	Flush Monitor 5 Location SoftTouch OneTouch Wall Monitor
SMA-OT-OC-1	OneTouch Outlet Kit 1 Wall Cavity OneTouch Option NA
SMA-OT-OC-2	OneTouch Outlet Kit 2 Wall to Wall OneTouch Option NA
SMA-OT-OC-3B	OneTouch Outlet Vac Barb OneTouch Option NA
SMA-OT-OC-3B-2	OneTouch Outlet Vac Dual Barb OneTouch Option NA
SMA-OT-OC-3P	OneTouch Outlet Vac Permanent OneTouch Option NA
SMA-OT-OC-3Q	OneTouch Outlet Vac Quick Disconnect OneTouch Option NA
SMA-OT-OC-3Q-2	OneTouch Outlet Vac Quick Disconnect OneTouch Option NA
SMA-OT-PW	Plenum Wire w/connectors Wire Sold Per Foot NA
SMA-OT-PW-KIT	Crimp Tool and 12 connectors for crimping end of wire
SMA-OT-TABLE	Predrilled Pump Mounts SMA-OT Table NA

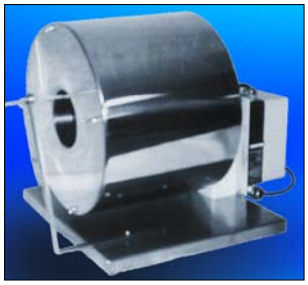
ROTAMETERS

Order#	Description
SMA-ROT-SS-1050	Stainless Calibration ROTAMETER 0-150 SCFH 'J1050' Calibration unit
SMA-ROT-SS-120	Stainless Steel ROTAMETER 0-150 SCFH 'J514' NA
SMA-ROT-SS-60	Stainless Steel ROTAMETER 0-90 SCFH 'J860' NA
SMA-ROT-SS-60-MD	Stainless Steel ROTAMETER 0-90 Modified 'J860' for Site Flow Verification For Site Calibration
SMA-ROT-SS-70	Stainless Steel ROTAMETER 0-70 SLPM 'J511' NA

HELMKE-YEICH TUMBLE DRUM TESTER

Order#	Description
HYE-101	Tumble Drum Only
HYEDR-100	Helmke-Yeick Tumble Drum Tester

HELMKE-YEICH™ TUMBLE DRUM TESTER



The Helmke-Yeich Tumble Drum Tester is used for disseminating the particulate and shedding features of products deemed suitable for the clean room environment. The H-Y Tumble Drum Tester is used by a majority of clean room laundries, pharmaceutical, biotechnology, semiconductor and electronic organizations worldwide. The unit is recommended by the Institute of Environmental Sciences (IES-RP3) for testing garments, wipers, gloves, and other clean room ready products.

Features of the H-Y Tumble Drum Tester:

- The H-Y Drum Is Mirror finished stainless steel both inside and outside
- The H-Y Tumble Drum has removable baffles for easy cleaning
- A Sealed Direct Drive Motor Assembly assures no particulate generation from the motor and assembly that may effect testing
- Variable Speed Control is standard with the unit with an optional digital speed readout
- The Stainless Steel Particle Counter introductory tube used to measure air in the drum does not affect the rotation and natural tumbling of product tested
- The H-Y base and risers are made of mirror finished stainless steel
- The unit is sized at: Drum: 17 inch L X 13 inch D Base: 18 inch L X 18 inch W Shipment Crate: 24 inch H X 18 inch W X 18 inch L

Testing with the H-Y Tumble Drum Tester

The entire unit is first purged in a laminar flow hood or controlled area. The unit incorporates a stainless steel particle counter connection on the exterior of the drum. This connection, with 3/8 inch ID PVC tubing, to the particle counter enables the operator to sample air inside the drum and evaluate the baseline contamination levels prior to beginning testing. As the Drum spins in the Class 100 laminar flow area, background counts will begin to drop. In approximately 5 minutes of initial purging, background counts will reach a suitable level to begin testing. These background levels are recorded prior to each test and the product to be tested is introduced and tested for a one (1) minute period. Five (5) additional readings for each product are recorded and averaged. The results will depict the level of contamination that the product will emit to the clean room environment per minute. Acceptable levels for varying clean room conditions are described in the IES RP3 monograph.

Order#	H-Y Tumble Drum Description
HYEDR-100	H-Y Tumble Drum w/dial control, variable speed
HYE-101	H-Y Drum Only.
HYE-102	Replacement H-Y Dial Speed Controller
HYE-104	H-Y Drive Shaft and Plate attachment for Drum

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

H-Y Tumble Drum Tester Manual
Technical Data File

610-644-8335

VTC™ VARIABLE TEMPERATURE CONTROLLER

FOR HIGH TEMPERATURE AIRBORNE PARTICULATE ANALYSIS

FEATURES:

- Designed to address the existent particulates incorporated in air and gas in excess of 1250°F
- Capable of reducing air/gas from 1250°F to 70°F in 36 inches
- Enables conducting of routine or continuous testing for airborne nonviable particulates in combination with any particle counter system
- Permits routine or continuous air/gas sampling measurements to be conducted in areas such as sterilizing tunnels, batch sterilizers, depyrogenation ovens, ovens, autocloves and many other high temperature related environments
- Removes the possibility of the potential unknown condition that may cause rejection or reinspection
- Permits particulate matter evaluations to be conducted on a real time basis
- Provides pre-evaluation data concerning areas
- Available in single and multi location (5) sampling systems
- Customer designs are available upon request (maximum 30 locations)
- Incorporates Stainless Steel connections
- Available in 115V AC or 220V AC (50/60 Hz)
- Can be permanently installed or placed on wheels for easy portability

Order#	Description
VTC-01	VTC-1 Location Sampler with easy connect to Particle Counter
VTC-05	VTC-5 Location Sampler with easy connect to Particle Counter

610-644-8335

WELCOME TO DPMD

DISPOSABLE PRODUCTS MANUFACTURING DIVISION

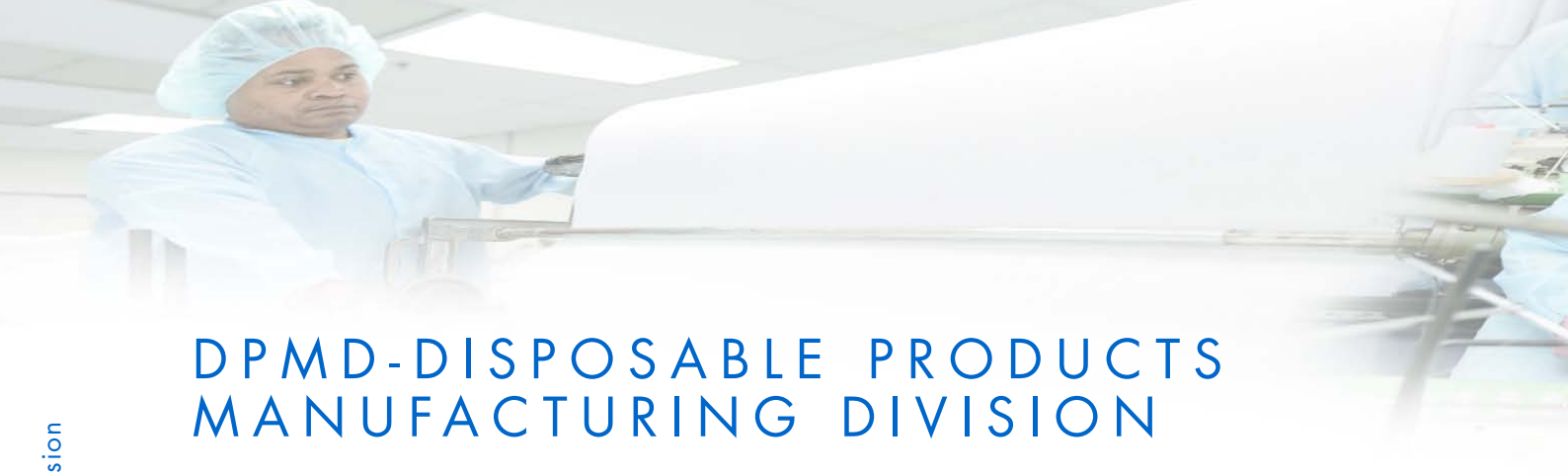
DPMD or VAI's Disposable Products Manufacturing Division has addressed the needs of the Pharmaceutical, Biotechnology, Semi-Conductor, and Electronics industries by designing a complete range of sterile and non-sterile disposable garments, textile products, and UCAN packaging which are manufactured under the CMP Clean Manufacturing System. The CMP Clean Manufacturing System incorporates Cutting, Manufacturing, and Packaging (CMP) all products within a Class 1000 clean room facility from beginning to end. This manufacturing style assures that all products are handled in the cleanest fashion available for this type of operation. Subsequently, VAI products have tested for over 15 years as one of the lowest particulate inherent products in the marketplace.

VAI's DPMD manufactures over 200 products which are designed for varying applications and clean room settings from Class 100 to Class 100,000. All DPMD products are manufactured in lot sequence, completely traceable and are tested for cleanliness by lot using our H-Y Tumble Drum Tester. This is in accordance with the Institute of Environmental Sciences Helmke Tumble™ Drum, IES-RP3.

DPMD incorporates internally designed material blends which have excellent barrier filtration capabilities, cleanliness and are designed for user comfort. DPMD also manufactures products with alternate material blends if requested.

DPMD has responded and met the demands of professionals in the industry for over 15 years. Our custom manufacturing capabilities assure that the client will be able to request changes to our standard products and have custom items manufactured specifically for their needs.

DPMD has its strongest position in the pharmaceutical and biotechnology industries. All sterile DPMD products are gamma irradiated. All systems are validated and appropriate documentation for products are assumed mandatory with delivery of the product. Our custom packaging provides packaging ranging from individual to bulk.



DPMD-DISPOSABLE PRODUCTS MANUFACTURING DIVISION

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UCAN™ PACKAGING NYLON

STERILIZATION AND CLEAN PACKAGING MATERIAL

UCAN FEATURES:

- Packaging material for sterilizing components
- Packaging for clean products
- Nylon based material
- Incorporates the lowest particulates levels in the marketplace
- Available in bags or rolls
- Manufactured through a blowing process that utilizes Class 100, 0.2 micron feed air
- Roll material is blown and placed directly onto the roll without the possible intervention of contaminants to the inside of the material
- All bags have a single seal at the bottom
- Can withstand temperatures in excess of 475°C
- Can be easily sealed using any high impact heat sealer
- Tested in accordance with ASTM standard for cleanliness
- Completely validated for steam penetration in confirming efficacy during sterilization processes

UCAN STERILIZATION USES:

- Component parts
- Porous and non-porous items
- Bowls
- Aseptic connections
- Sanitary fittings
- Sampling tubes
- Stainless and aluminum parts
- HDPE
- Other items requiring a clean bag and seal system prior to entry into a Class 100 area

Order#	Description	Quan/cs.
UC-12	UCAN Roll 12" Wide	6
UC-15	UCAN Roll 15" Wide	4
UC-20	UCAN Roll 20" Wide	4
UCAN-2x6	UCAN Bags 2"x6"	3,000
UCAN-5x10	UCAN Bags 5"x10"	1,000
UCAN-15x20	UCAN Bags 15"x20"	500
UCAN-18x24	UCAN Bags 18"x24"	500
UCAN-20x30	UCAN Bags 20"x30"	500

*Sterile UCAN available upon request

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

Product Validation
UCAN Technical Data File

CMP™ CLEAN GARMENT MATERIAL BLENDS

The Disposable Products Manufacturing Division (DPMD) has been in existence and serving the pharmaceutical, biotechnology, semiconductor and electronics industries for over 25 years. All products are Cut, Manufactured and Packaged (CMP) in a clean room from beginning to end. DPMD manufactures a complete line of disposable protective garments that includes various styles.

The following material blends are utilized in the manufacturing of our products:

PF-1 Material Blend:

- Manufactured into face masks and bouffant hats
- Soft, comfortable and breathable material
- Designed for use in Class 100 to 1,000 areas
- Rayon material coated with VAI's patented latex binder
- Very low particulate and shedding features
- Filtration or retentive properties of the material measured at 0.45 microns is 96%
- Designed for use in semiconductor or electronic operations

PF-2 Material Blend:

- Manufactured into face masks
- Soft, comfortable and breathable material
- Rayon material coated with VAI's patented latex binder
- Very low particulate and shedding features
- Filtration or retentive properties of the material measured at 0.45 microns is 99%
- Designed for pharmaceutical and biotechnology operations

PF-3 Material Blend:

- Manufactured into face masks
- Soft, comfortable and breathable material blend in a two-ply rayon-polypropylene that is coated with VAI's patented latex binder
- Very low particulate and shedding features
- Filtration or retentive properties of the material measured at 0.45 microns is 99%
- Designed as a fluids barrier

1420 Mitcool Material Blend:

- Manufactured into coveralls, lab coats, shoe covers and bouffant hats
- Soft, comfortable and breathable heat-bonded polypropylene
- Designed for use in Class 1,000 to 100,000 areas
- Filtration and efficiency or retentive properties of the material measured at 0.45 microns is 91%

1600 Mitcool Material Blend:

- Manufactured into coveralls, lab coats, hoods, sleeves and mid-calf boots
- Soft, comfortable and breathable material is single sewn with bound edges
- Heat-bonded polypropylene that is coated with VAI's patented latex binder
- Designed for use in Class 100 sterile and non-sterile areas
- Very low particulate and shedding features
- Filtration and efficiency or barrier retention is measured at 0.45 microns is 99%
- Used widely in sterile gowning material used in aseptic manufacturing operations

CMP™ CLEAN GARMENT MATERIAL BLENDS cont'd

CoolZone Material Blend:

- Manufactured into coveralls, lab coats, hoods, sleeves and mid-calf boots
- Soft, comfortable and breathable material
- Integrates complete double stitch (French seam) sewing throughout the gown
- Heat-bonded 3-ply polypropylene that is coated with VAI's patented latex binder
- Designed for use in Class 100 sterile and non-sterile areas
- Very low particulate and shedding features
- Filtration and efficiency or barrier retention of the material measured at 0.45 microns is 99%
- Most widely used sterile gowning material in aseptic manufacturing operations

1700 CleanBlend Material Blend:

- Manufactured into coveralls, lab coats, hoods, sleeve and mid-calf boots
- Soft and comfortable material
- Single stitch sewn with bound edges
- Heat-bonded polypropylene that is laminated with VAI's patented laminate binding material
- Designed for use in either Class 100 sterile or non-sterile areas and as a personal protection garment
- Very low particulate and shedding features
- Filtration and efficiency or barrier retention of the material measured at 0.45 microns is 100%
- Most widely used as a personal protection gown since it has excellent chemical resistance to a variety of agents

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

Garment Product Validation
Technical Data File

CMP™ GARMENT STYLES

The CMP Garments provide excellent barrier capabilities. The CMP Garment products are soft, cool and comfortable and reduce user discomfort. Available in many styles presented below, the CMP Garments are the choice of many pharmaceutical, biotechnology, semiconductor and electronic organizations in the industry.

Choosing a Material Blend:

1300 is used in Class 10,000-100,000 non-sterile operations.
1420 is used in Class 1,000-100,000 non-sterile operations.
1600 is used in Class 100 sterile and non-sterile operations.

Choosing a Packaging Option:

All VAI CMP Garments are available both sterile and non-sterile. All sterile products are packaged individually per garment, and are lot coded during manufacturing and sterilization (sterile documentation accompanies all orders). Please contact VAI Customer Service for packaging options. Ordering Instructions are presented on the last page of the DPMD section.

Bouffant Hat

Under Chin Hood

Non-Skid Sole

Shoecover Non-Skid

Midcalf Boot

Lab Coat

Complete Coverage

PF FACE MASK™ STYLES

Surgical Mask
with elastic

PF FACE MASK FEATURES:

- Excellent barrier capabilities
- Soft, cool and comfortable
- Eliminate goggle fogging
- Available in many styles

CHOOSING A MATERIAL BLEND:

- PF-2 is used in pharmaceutical and biotechnology operations as a sterile mask

CHOOSING A PACKAGING OPTION:

- Available sterile and non-sterile
- All sterile products are packaged individually per mask
- All sterile products are lot coded during manufacturing and sterilization
- Sterile products all come with complete sterilization documentation

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

Face Mask Product Validation
Technical Data File

Surgical Mask
with ties

Surgical Mask Long
with ties

GARMENT ORDERING

DISPOSABLE PACKAGING & STERILIZATION

All VAI disposable products are available in packaging from bulk case to individual packs, in both sterile and non-sterile form. Sterilization is done via gamma radiation and complete documentation is provided upon delivery.

VAI Shoe Coverings

Order #	Description	Size	STERILE/ NON STERILE	Q/CS
150-SC-NS-1502	LOW CUT SHOECOVERS WITH NON-SKID SOLE	S/M	NS	125 PAIR
150-SC-NS-1503	LOW CUT SHOECOVERS WITH NON-SKID SOLE	L/XL	NS	125 PAIR
150-SC-NS-1504	LOW CUT SHOECOVERS WITH NON-SKID SOLE	XXL/XXXL	NS	125 PAIR
150MC-1505	STANDARD BOOTS	S/M	NS	100 PAIR
150MC-1506	STANDARD BOOTS	L/XL	NS	100 PAIR
1600MC-NC-1664	MID CALF BOOTS VINYL SOLE	L/XL	NS	50 PAIR
1600MC-NS-1665	MID CALF BOOTS VINYL SOLE	XXL/XXXL	NS	50 PAIR
1600MC-NS-S-1666	MID CALF BOOTS NON-SKID SOLE	S/M	S	50 PAIR
1600MC-NS-S-1667	MID CALF BOOTS WITH NON-SKID SOLE	L/XL	S	50 PAIR
1600MC-NS-S-1668	MID CALF BOOTS WITH NON-SKID SOLE	XXL/XXXL	S	100 PAIR
1600MC-NS-1663	MID CALF BOOTS WITH NON-SKID SOLE	S/M	NS	50 PAIR
150-SC-1501	LOW CUT SHOECOVERS WITH NON-SKID SOLE	ONE SIZE	NS	150 PAIR
150-SC-NS-1512	LOW CUT SHOECOVERS WITH NON-SKID SOLE	S/M	NS	125 PAIR
150MC-1507	STANDARD BOOTS	XXL/XXXL	NS	100 PAIR
150MC-NS-1508	NON-SKID SOLE BOOTS	S/M	NS	100 PAIR
150MC-NS-1509	NON-SKID SOLE BOOTS	L/XL	NS	100 PAIR
150MC-NS-1510	NON-SKID SOLE BOOTS	XXL/XXXL	NS	100 PAIR

VAI Coveralls and Labcoats

Order #	Description	Size	STERILE/ NON STERILE	Q/CS
1600-E-S-1607	COVERALL WITH ELASTIC WRIST AND ARMS MITCOOL FABRIC	S	S	25
1600-E-S-1608	COVERALL WITH ELASTIC WRIST AND ARMS MITCOOL FABRIC	M	S	25
1600-E-S-1609	COVERALL WITH ELASTIC WRIST AND ARMS MITCOOL FABRIC	L	S	25
1600-E-S-1610	COVERALL WITH ELASTIC WRIST AND ARMS MITCOOL FABRIC	XL	S	25
1600-E-S-1611	COVERALL WITH ELASTIC WRIST AND ARMS MITCOOL FABRIC	XXL	S	25
1600-E-S-1612	COVERALL WITH ELASTIC WRIST AND ARMS MITCOOL FABRIC	XXXL	S	25
1600-E-S-1687	COVERALL WITH ELASTIC WRIST AND ARMS MITCOOL FABRIC	5XL	S	25
1600-EHB-S-1632	COVERALL WITH ELASTIC WRIST, ARMS AND ATTACHED HOOD AND BOOTS	M	S	25
1600-EHB-S-1633	COVERALL WITH ELASTIC WRIST, ARMS AND ATTACHED HOOD AND BOOTS	L	S	25
1600-EHB-S-1634	COVERALL WITH ELASTIC WRIST, ARMS AND ATTACHED HOOD AND BOOTS	XL	S	25

GARMENT ORDERING cont'd

VAI Coveralls and Labcoats, continued

Order #	Description	Size	STERILE/ NON STERILE	Q/CS
1600-EHB-S-1635	COVERALL WITH ELASTIC WRIST, ARMS AND ATTACHED HOOD AND BOOTS	XXL	S	25
1600-EHB-S-1636	COVERALL WITH ELASTIC WRIST, ARMS AND ATTACHED HOOD AND BOOTS	XXXL	S	25
1600-EHB-S-1686	COVERALL WITH ELASTIC WRIST, ARMS AND ATTACHED HOOD AND BOOTS	5XL	S	20
1600-LC-S-1644	LAB COAT WITH ZIPPER, ELASTIC WRIST MITCOOL FABRIC	M	S	25
1600-LC-S-1645	LAB COAT WITH ZIPPER, ELASTIC WRIST MITCOOL FABRIC	L	S	25
1600-LC-S-1646	LAB COAT WITH ZIPPER, ELASTIC WRIST MITCOOL FABRIC	XL	S	25
1600-LC-S-1647	LAB COAT WITH ZIPPER, ELASTIC WRIST MITCOOL FABRIC	XXL	S	25
1600-LC-S-1648	LAB COAT WITH ZIPPER, ELASTIC WRIST MITCOOL FABRIC	XXXL	S	25
1600-PS-S-1650	PROTECTIVE SLEEVES WITH ELASTIC AT BOTH ENDS	ONE SIZE	S	200 PAIR
1600-E-1601	COVERALL WITH ELASTIC WRIST AND ARMS MITCOOL FABRIC	S	NS	25
1600-E-1602	COVERALL WITH ELASTIC WRIST AND ARMS MITCOOL FABRIC	M	NS	25
1600-E-1603	COVERALL WITH ELASTIC WRIST AND ARMS MITCOOL FABRIC	L	NS	25
1600-E-1604	COVERALL WITH ELASTIC WRIST AND ARMS MITCOOL FABRIC	XL	NS	25
1600-E-1605	COVERALL WITH ELASTIC WRIST AND ARMS MITCOOL FABRIC	XXL	NS	25
1600-E-1606	COVERALL WITH ELASTIC WRIST AND ARMS MITCOOL FABRIC	XXXL	NS	25
1600-E-1685	COVERALL WITH ELASTIC WRIST AND ARMS MITCOOL FABRIC	5XL	NS	25
1600-EHB-1625	COVERALL WITH ELASTIC WRIST, ARMS AND ATTACHED HOOD AND BOOTS	S	NS	25
1600-EHB-1626	COVERALL WITH ELASTIC WRIST, ARMS AND ATTACHED HOOD AND BOOTS	M	NS	25
1600-EHB-1627	COVERALL WITH ELASTIC WRIST, ARMS AND ATTACHED HOOD AND BOOTS	L	NS	25
1600-EHB-1628	COVERALL WITH ELASTIC WRIST, ARMS AND ATTACHED HOOD AND BOOTS	XL	NS	25
1600-EHB-1629	COVERALL WITH ELASTIC WRIST, ARMS AND ATTACHED HOOD AND BOOTS	XXL	NS	25
1600-EHB-1630	COVERALL WITH ELASTIC WRIST, ARMS AND ATTACHED HOOD AND BOOTS	XXXL	NS	25
1600-EHB-S-1631	COVERALL WITH ELASTIC WRIST, ARMS AND ATTACHED HOOD AND BOOTS	S	S	25
1600-EHB-S-1687	COVERALL WITH ELASTIC WRIST, ARMS AND ATTACHED HOOD AND BOOTS	3XL	S	20
1600-EHB-S-1688	COVERALL WITH ELASTIC WRIST, ARMS AND ATTACHED HOOD AND BOOTS	5XL	S	20
1600-LC-1637	LAB COAT WITH ELASTIC WRIST AND ZIPPER MITCOOL FABRIC	S	NS	25
1600-LC-1638	LAB COAT WITH ELASTIC WRIST AND ZIPPER MITCOOL FABRIC	M	NS	25
1600-LC-1639	LAB COAT WITH ELASTIC WRIST AND ZIPPER MITCOOL FABRIC	L	NS	25
1600-LC-1640	LAB COAT WITH ELASTIC WRIST AND ZIPPER MITCOOL FABRIC	XL	NS	25
1600-LC-1641	LAB COAT WITH ELASTIC WRIST AND ZIPPER MITCOOL FABRIC	XXL	NS	25
1600-LC-1642	LAB COAT WITH ELASTIC WRIST AND ZIPPER MITCOOL FABRIC	XXXL	NS	25
1600-LC-S-1643	LAB COAT WITH ELASTIC WRIST AND ZIPPER MITCOOL FABRIC	S	S	25
1600-PS-1649	PROTECTIVE SLEEVES WITH ELASTIC AT BOTH ENDS	ONE SIZE	NS	200 PAIR

GARMENT ORDERING cont'd

VAI Face Masks and Head Coverings

Order #	Description	Size	STERILE/ NON STERILE	Q/CS
1600H-UC-S-1660	UNDER CHIN HOOD	S/M	S	100
1600H-UC-S-1661	UNDER CHIN HOOD	L/XL	S	100
1600H-UC-S-1662	UNDER CHIN HOOD	XXL/XXXL	S	100
PF-2F-T-4-2014	FLAT FACE MASK WITH 4 TIES	L	S	500
PF-2SM-2-S-2025	SURGICAL MASK WITH 2 ELASTICS	ONE SIZE	S	500
PF-2SM-T-4-S-2021	SURGICAL MASK WITH 4 ELASTICS	ONE SIZE	S	500
PP28-2451	BOUFFANT HAT	ONE SIZE	NS	250
PF-2SM-2-S-2026	SURGICAL MASK WITH 2 ELASTIC TIES FOAM NOSEPIECE 9"	ONE SIZE	S	500
PF-2SM-2-S-2027	SURGICAL MASK WITH 2 ELASTIC TIES FOAM NOSEPIECE 9"	ONE SIZE	NS	500
PF-2SM-2-S-2028	SURGICAL MASK WITH 2 ELASTIC TIES FOAM NOSEPIECE 9"	ONE SIZE	NS	500
1600H-EO-1651	HOOD WITH EYE OPENINGS	S/M	NS	100
1600H-EO-1652	HOOD WITH EYE OPENINGS	L/XL	NS	100
1600H-EO-1653	HOOD WITH EYE OPENINGS	XXL/XXXL	NS	100
1600H-EO-S-1654	HOOD WITH EYE OPENINGS	S/M	S	100
1600H-EO-S-1655	HOOD WITH EYE OPENINGS	L/XL	S	100
1600H-EO-S-1656	HOOD WITH EYE OPENINGS	XXL/XXXL	S	100
1600H-UC-1657	UNDER THE CHIN HOOD	S/M	NS	100
1600H-UC-1658	UNDER THE CHIN HOOD	L/XL	NS	100
1600H-UC-1659	UNDER THE CHIN HOOD	XXL/XXXL	NS	100
PF-2F-T-4-S-2012	FLAT MASK WITH 4 TIES	S	S	500
PF-2F-T-4-S-2013	FLAT MASK WITH 4 TIES	S	S	500
PF-2F-T-4-S-2015	FLAT MASK WITH 4 TIES	L	S	500
PF-2SM-1-S-2016	SURGICAL MASK WITH 1 ELASTIC	ONE SIZE	S	500
PF-2SM-2-2017	SURGICAL MASK WITH 2 ELASTICS	ONE SIZE	NS	500
PF-2SM-2-S-2018	SURGICAL MASK WITH 2 ELASTICS	ONE SIZE	S	500
PF-2SM-2-S-2019	SURGICAL MASK WITH 2 ELASTICS	ONE SIZE	S	500

VAI LABS

VAI Laboratories

610-644-8335

WELCOME TO VAI LABORATORIES

VAI Laboratories closes the gap of required regulatory documentation by providing contract microbe identification and antimicrobial effectiveness studies that are performed on either one's internal environmental isolates or ATCC cultures against the chosen array of disinfecting agents.

As time constraints and the availability of personnel within GMP firms may be unavailable to conduct these extremely important studies, one can now have VAI Laboratories complete these items on a contract basis.

The identification of microbial contaminants is completed, per the customer's specifications, either by fatty acid or genetic sequencing techniques. Identification of the organism is the first step to designing a corrective action plan to destroy its existence in controlled environments.

Subsequently, the need to verify the antimicrobial effectiveness of disinfecting agents used in control environments is a critical step to assuring a documented disinfection system is in place. VAI Laboratories conducts either time contact kill studies on standard or user surfaces and AOAC protocol testing studies. All tests are performed in triplicate and done at three specified contact (dry time) time periods. A complete report of the study is presented to the end user to complete their documentation file for internal or external audit requirements.

VAI Laboratories is a value-added service available through Veltek Associates, Inc. that not only completes required testing but also provides an invaluable source of information from experienced laboratory and disinfection professionals who are involved daily in GMP settings.

VAI® LABS

VAI Laboratories was established to assist our customers by providing microbiological testing services ranging from the identification of microorganisms to antimicrobial effectiveness studies to prove the effectiveness of selected disinfectants.

The successful operation of a clean room environment is dependent on the exactness of the information available and the implementation of a plan of action from such information. Pharmaceutical, Biotechnology, and Healthcare professionals have been required by the FDA to address known contamination within their facility and develop a validated plan of action to remove such contamination. This requirement will not change in the future. In fact, qualifications for clean room operations will only become more stringent as time progresses.

The importance of addressing existent contaminants is a situation that requires much effort. Complete and documented efficacy performance testing and in-situation testing to prove the removal of existent contamination is a very costly and time-consuming task. To date, there has been no completely encompassing alternative provided in the marketplace that can provide services from identification of an organism to effective destruction of the organism from the environment. Thus, microbiologists are continually forced to focus efforts on basic laboratory services that are costly and time consuming.

VAI has responded to the needs of our clients by installing GLP laboratories focusing in the area of microbiological testing services. Customized to the users requests, VAI laboratory testing division is capable of performing the following services in conjunction with the use of VAI products:

Time Contact Kill Studies: Request VAI Technical Document: VAI-TCK-01

ATCC cultures and/or cultures obtained from the customer (environmental isolates) will be tested over a specified contact time. The results obtained will demonstrate the effectiveness or lack of effectiveness of the disinfectant tested against the suspended organism culture. All data is then compiled into a report per organism.

Disinfectant Validation Services: Request VAI Technical Document: VAI-TVAL-01

An expanded and more encompassing service than the time contact kill studies listed above is the Disinfectant Validation Service. In conjunction with the customer's needs, VAI will test specified disinfectants against a variety of ATCC cultures and cultures obtained by the customer (environmental isolates). Testing will specify a contact time. The results obtained will demonstrate the effectiveness or lack of effectiveness of the disinfectant tested against the suspended organism culture. All data is then compiled into one report and will provide an effective means to address regulatory concerns for addressing contamination within one's operations.

Microbe Identification Services: Request VAI Technical Document: VAI-IDE-01

Fatty acid composition of individual species, and even subspecies, of bacteria and other microbes can serve as a stable and reliable identifying characteristic. The Microbial Identification System (MIS) capitalizes on this knowledge and uses state-of-the-art technology to render the profile of the microbe.

Consulting: Request VAI Technical Document: VAI-CSS-01

The design of a biodecontamination system warrants experience and familiarization with disinfection systems that have proven success in the control of microbial and particulate contamination in clean room environments. VAI has the experience and the personnel to completely evaluate operations and address the needed requirements for operation of the controlled areas.

WELCOME TO CORE2CLEAN

SPRAY • MOP • FOG DISINFECTANT APPLICATION SYSTEMS

The adequate application of the disinfectant or sporicide to the surface is the final and most important step in assuring the demise of existent viable contaminants in our controlled environments. Once we leave the validation study scenario, we are confronted with the complex situation of implementing what we have proven as acceptable into the real-life scope of our operations. Maintaining a system that is meaningful, manageable and defendable becomes complex in production areas as we encounter a multitude of variables. The Core2Clean Systems are designed to address the application of cleaning and disinfecting agents to the surface in a meaningful and manageable methodology. Specifically designed for pharmaceutical, biotechnology and healthcare facilities, the Core2Clean Systems simplify application within controlled areas.

The Core2Clean Systems were invented by Veltek Associates, Inc. to address this application requirement. Sometimes one needs to spray, sometimes to mop and at times a fogger needs to be utilized. The Core2Clean Systems incorporate all three in to one. The systems incorporate a trigger-activated sprayer, a trigger activated sponge mop and a fogger all in one unit. The key elements of the systems are the capability to present a sufficient amount of liquid to the surface and the capability of reducing cleaning time by nearly 50%. Introduction of all the items required to clean and disinfect an area are done at once as the entire unit can be autoclaved prior to entry. With this in mind, the Core2Clean Systems provide a simple mechanism to assure cleaning and disinfection is done in an effective and efficient manner.

CORE2CLEAN® SPRAY • MOP • FOG SYSTEMS

FOR THE APPLICATION OF DISINFECTING AGENTS IN CONTROLLED AREAS

The CORE2CLEAN Systems were designed to address the application of cleaning and disinfecting agents to the surface in a meaningful and manageable methodology. The CORE2CLEAN Systems have been specifically designed for pharmaceutical, biotechnology and healthcare facilities in their controlled environments. For years, the use of a conventional bucket and a mop or pad has been used to provide application of the chemical agent to the surfaces in controlled areas. In addition to mops/pad and buckets, facilities also incorporated a sprayer and a fogger within their cleaning and disinfecting operations. The CORE2CLEAN Systems eliminate the need for a multitude of components and incorporate them within one device.

- The CORE2CLEAN Systems are made of 304-316 stainless steel and can be steam sterilized to eliminate the concerns for introduction of viable contamination to the controlled environment from the components themselves.
- The CORE2CLEAN Systems are compressed air operated (ASME rated to 100 psi). This provides the ability to dispense a continuous flow of a clean solution to the surface. Continuously providing a clean solution to the surface reduces cleaning time and end user effort.
- The CORE2CLEAN Systems eliminate the concerns for changing of dirtied cleaning solution. This eliminates the need to discard the dirtied solutions and reduces the volume of cleaning agents required to address one's surfaces annually.
- The CORE2CLEAN Systems incorporate a trigger activated dispensing mop, a sprayer and a fogger all in one unit.
- The CORE2CLEAN Systems present a sufficient wetting of the surface unavailable from other mopping systems. Increasing the time period the surface remains wet is essential to assuring efficacy performance of disinfecting agents.
- The CORE2CLEAN Systems can reduce cleaning time by 50% and is easily moved from area to area by a 4-wheel caster dolly that can be removed and cleaned.
- The CORE2CLEAN Systems utilize quick disconnects to attach the mop, sprayer and fogger. The CORE2CLEAN Systems are user friendly and simplify cleaning and disinfecting procedures.

The CORE2CLEAN Systems incorporate spray, mop and fog capabilities all in one unit. The
key elements of the systems are the capability to present a sufficient amount of liquid to the surface and the capability of reducing cleaning time by nearly 50%. With this in mind, the CORE2CLEAN Systems provide a simple mechanism to assure cleaning and disinfection is done in an effective and efficient manner.

AVAILABLE TECHNICAL DATA SUPPLEMENTS *(UPON REQUEST)*

C2C-2003-F1 CORE2CLEAN Manual
C2C-2000-C CORE2CLEAN Product Validation
C2C-2000-A1.PDF Technical Data File

610-644-8335

Basic Components

Order#	Description
C2C-102	2 gallon spray tank ready for connection to the C2C Spray Gun, Mop or Fogger Accessory. Includes: caster wheels, pressure gauge, and 15 ft autoclavable source and dispense pressure hose. (Includes C2C-100-1 Spray Gun)
C2C-105	5 gallon spray tank ready for connection to the C2C Spray Gun, Mop or Fogger Accessory. Includes: caster wheels, pressure gauge, and 15 ft autoclavable source & dispense pressure hose. (Includes C2C-100-1Spray Gun)
C2C-100-1	Spray Gun Accessory with Quick Disconnect Tip (included with the C2C-102 and C2C-105)
C2C-100-2 (7" = A) (12" = B)	Automatic Mop Accessory with Mophead base (7" or 12" with quick disconnect) and 3 foot extension arm (additional arms available).
C2C-100-3	Fogger with Quick Disconnect (5-50 micron droplet)

Spare Parts

Order#	Description
C2C-100-2-7	7' Bayonet Style Mop Frame
C2C-100-2-12	12' Bayonet Style Mop Frame
C2C-100-2-CL	Clamp for Bayonet Style Mop Frame
C2C-100-4A	Additional 15' Autoclavable Source Pressure Hose
C2C-100-4B	Additional 15' Autoclavable Pressure Output Hose
C2C-100-5	Replacement Quick Disconnect (Male & Female)
C2C-100-6	Replacement Gauge 5-200 psi.
C2C-100-6	Input Regulator Assembly with Gauge and Fittings
C2C-100-6-GO	1-100 Input Gauge only
C2C-100-6-OUT	Output Regulator Assembly with Gauge and Fittings
C2C-100-6-OUT-GO	0-60 Output Gauge only
C2C-100-15	Additional 10' Mop Handle Extension Accessory
C2C-100-16	Optional 7" Mophead Base (Mophead only)
C2C-100-17	Optional 12" Mophead Base (Mophead only)
C2C-100-18	Additional 3' Mop Handle Extension Accessory
C2C-100-18-120	120" Extension (Wand only)
C2C-100-18-18	18" Extension (Wand only)
C2C-100-18-36	36" Extension (Wand only)
C2C-100-24	Core2clean 12" Curtain Cleaner
C2C-100-22	Spray Tip Nozzle
C2C-100-25	Replacement Caster Wheels

C2C Mopheads

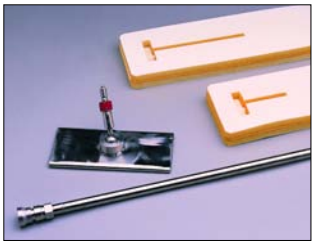
Order#	Description	Qty / Case
C2C-100-7	7" VertiKlean, Mophead for C2C System (Non-Sterile)	48
C2C-100-8	7" VertiKlean, Mophead for C2C System (STERILE)	48
C2C-100-9	12" VertiKlean, Mophead for C2C System (Non-Sterile)	32
C2C-100-10	12" VertiKlean, Mophead for C2C System (STERILE)	32
C2C-100-11	7" VertiKlean, VK-SOX Floor Cover for C2C (Non-Sterile)	32
C2C-100-12	7" VertiKlean, VK-SOX Floor Cover for C2C (STERILE)	32
C2C-100-13	12" VertiKlean, VK-SOX Floor Cover for C2C (Non-Sterile)	120
C2C-100-14	12" VertiKlean, VK-SOX Floor Cover for C2C (STERILE)	120

VertiKlean® is a registered trademark of Contec, Inc,

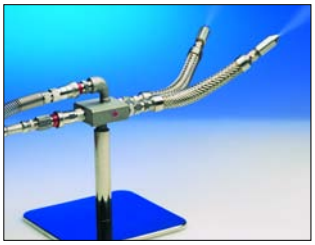
Features of the Core2Clean Systems

Quick Disconnect Sprayer

Quick Disconnect Mop



7 or 12 inch mop-heads and 3 and 10 foot mop extensions



Quick Disconnect Fogger

610-644-8335

WELCOME TO ASEPTIC PROCESSING, INC.

A DIVISION OF VELTEK ASSOCIATES, INC.

Since 1981, Veltek Associates, Inc. (VAI) has played an innovative role to the pharmaceutical, biotechnology and medical device industries by partnering with clients to develop strategic products and service that have improved operations and reduced costs associated with the ingress of contamination. During the history of the company, VAI has manufactured and developed over 500 strategic and critical contamination control products, systems and services. These innovative solutions are used by most GMP organizations worldwide.

In the over two decades of operations, VAI has not only developed innovative products and services but also the know how for assuring successful and compliant systems to monitor and control contamination.

After many years of refinement and development, VAI introduced, in the year 2001, a unique and specialized value added advantage for it's clientele know as VAI Consulting Services. In 2003, due to its enormous growth, the division was reorganized into Aseptic Processing, Inc. (API). API is the consulting and training division of Veltek Associates, Inc.

The mission and key focus of the division is to lead the industry in specific contamination control and environmental monitoring systems. Unlike many consulting organization, API focuses specifically in the areas of Cleaning and Disinfection Systems, Disinfectant Validation Services, Component Entry Systems, Environmental Monitoring Systems, Aseptic Processing Systems, Media Fills, and Personnel Training Systems. API has assisted a multitude of pharmaceutical, biotechnology, and medical device organizations worldwide. API was also responsible for the cleaning and disinfection training that was conducted to the U.S. Food and Drug Administration's CDER and CBER divisions in 2001-2004.

Uniquely, the division works to combine all contamination control aspects within an organization into one system that is both compliant, effective and assures repeatable success.

Specialized Consulting Services in the areas of:

- Environmental Monitoring Systems
- Cleaning/Disinfection Systems
- Personnel Gowning Systems
- Aseptic Processing Systems
- Component Entry Systems
- Personnel Training
- Media Fill Trials

ASEPTIC PROCESSING, INC

EXPERT SERVICES

API provides a wide range of technical services to the pharmaceutical and biotechnology industries. Our experience encompasses the following critical areas:

Cleaning & Disinfection and Component Entry Systems

Review of current and future practices, advanced technology; cleaning of controlled and non-controlled areas; equipment cleaning and disinfection; disinfectant and sporicidal qualifications and validations; cleaning practices and methods of application; contamination control practices; residue removal; clean in place systems (CIP); sterilize in place systems (SIP); component entry systems; compliance assurance and training of personnel.

Environmental Monitoring, Media Fills and Airflow Studies

Review of current and future technology; development of air, surface and personnel programs; qualification of controlled environments; validation; compliance assurance; conducting investigations; corrective actions; media fills; air flow studies and training of personnel.

Aseptic Processing

Review of current and future practices, advanced technology; review of aseptic practices; regulatory compliance; facility design; aseptic filling; terminal sterilization; and in-house training of personnel.

Personnel Gowning

Personnel gowning for controlled and non-controlled environments; qualifications; aseptic practices; gown training programs and training of personnel.

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PURCHASING PRODUCTS AND AVAILABLE TECHNICAL DOCUMENTATION

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Technical Support:

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Technical Documentation:

Technical documentation for each product is available via e-mail, fax or CD in Adobe Acrobat PDF format. This includes product specifications, testing and Material Safety Data Sheets.

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